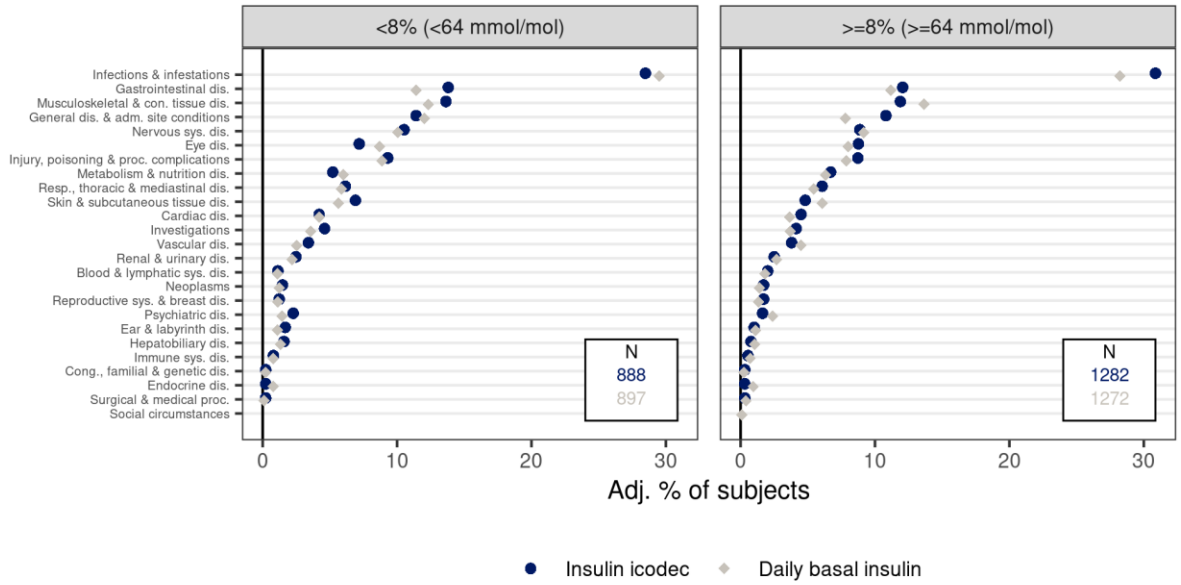
## 7.7.45 Adverse events by baseline HbA1c group and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

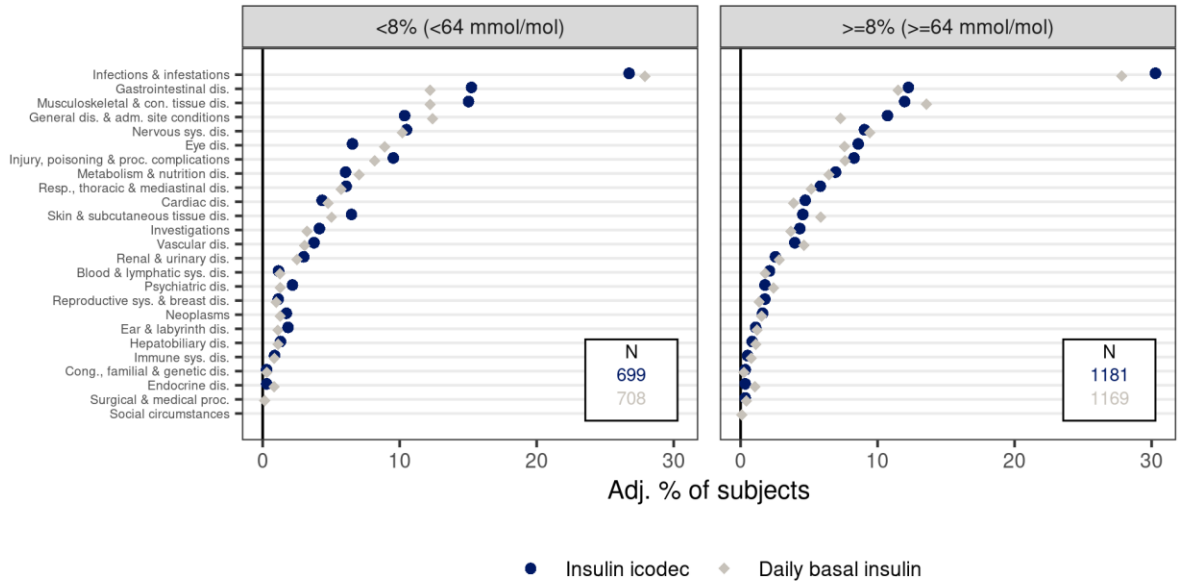



% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): HBAGR1; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS HBAGR1; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:55 - faedotgrp/faesocgrphba1cdotontp3asas.png

## 7.7.46 Adverse events by baseline HbA1c group and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool

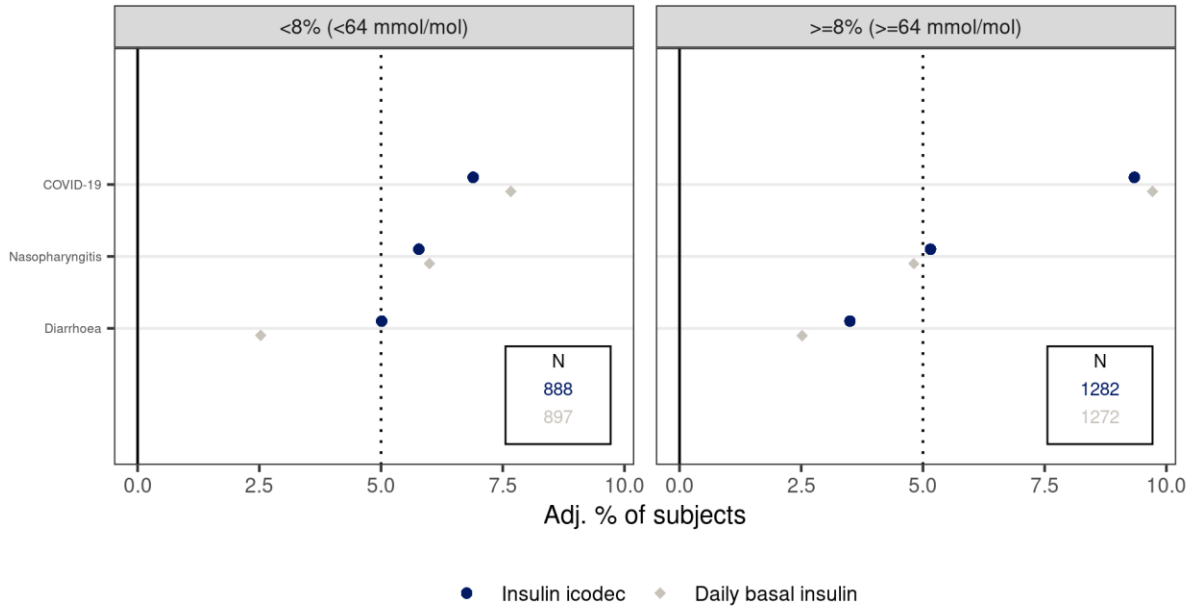



% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): HBAGR1; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS HBAGR1; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:59 - faedotgrp/faesocgrphba1cdotontt2dsas.png

## 7.7.47 Adverse events by baseline HbA1c group and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

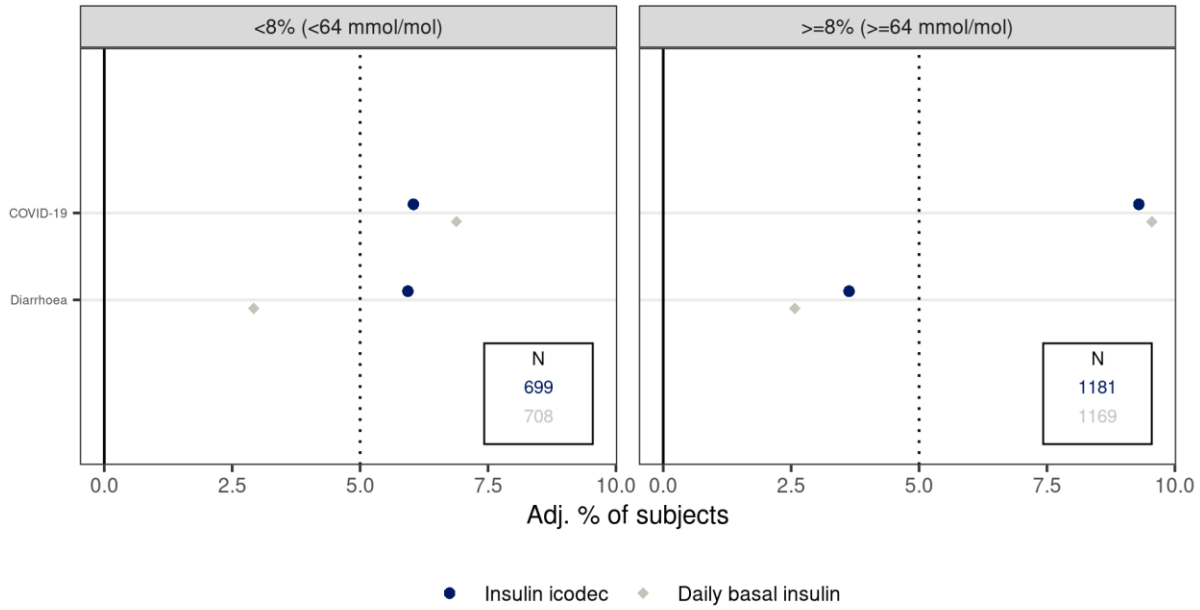



% of subjects: Percentage of subjects with one or more events, N: Number of subjects. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): HBAGR1; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD HBAGR1; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:04 - faedotgrp/faept5pctgrphba1cdotontp3asas.png

## 7.7.48 Adverse events by baseline HbA1c group and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool




% of subjects: Percentage of subjects with one or more events, N: Number of subjects, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): HBAGR1; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD HBAGR1; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:09 - faedotgrp/faept5pctgrphba1cdotontt2dsas.png

## 7.7.49 Adverse events by diabetes duration - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <10 years | 764 | | | | 796 | | | |
| >=10 years | 1406 | | | | 1374 | | | |
| PYE (years) | | | | | | | | |
| <10 years | 626.99 | | | | 656.89 | | | |
| >=10 years | 1054.24 | | | | 1023.69 | | | |
| Events | | | | | | | | |
| <10 years | 445 | (58.3) | 1357 | 231.03 | 467 | (58.6) | 1399 | 230.15 |
| >=10 years | 883 | (62.8) | 2628 | 267.37 | 796 | (58.0) | 2479 | 262.93 |
| Serious | | | | | | | | |
| Yes | | | | | | | | |
| <10 years | 47 | ( 6.1) | 66 | 10.68 | 55 | ( 6.8) | 71 | 11.16 |
| >=10 years | 119 | ( 8.4) | 179 | 16.95 | 114 | ( 8.3) | 167 | 15.16 |
| No | | | | | | | | |
| <10 years | 431 | (56.5) | 1291 | 220.35 | 456 | (57.2) | 1328 | 218.99 |
| >=10 years | 856 | (60.9) | 2449 | 250.43 | 767 | (55.9) | 2312 | 247.77 |
| Missing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Severity | | | | | | | | |
| Severe | | | | | | | | |
| <10 years | 26 | ( 3.4) | 33 | 5.97 | 29 | ( 3.6) | 37 | 5.74 |
| >=10 years | 66 | ( 4.7) | 88 | 8.60 | 60 | ( 4.4) | 96 | 8.29 |
| Moderate | | | | | | | | |
| <10 years | 172 | (22.5) | 310 | 51.47 | 175 | (22.0) | 321 | 48.95 |
| >=10 years | 340 | (24.1) | 621 | 59.72 | 303 | (22.1) | 535 | 54.60 |
| Mild | | | | | | | | |
| <10 years | 379 | (49.7) | 1014 | 173.60 | 394 | (49.4) | 1041 | 175.47 |
| >=10 years | 734 | (52.2) | 1919 | 199.05 | 679 | (49.5) | 1848 | 200.04 |
| Missing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Related to basal insulin | | | | | | | | |
| Probable | | | | | | | | |
| <10 years | 34 | ( 4.5) | 61 | 11.48 | 32 | ( 4.0) | 52 | 8.85 |
| >=10 years | 48 | ( 3.4) | 59 | 6.57 | 44 | ( 3.2) | 81 | 7.62 |
| Possible | | | | | | | | |
| <10 years | 37 | ( 4.8) | 54 | 9.99 | 29 | ( 3.6) | 38 | 6.10 |
| >=10 years | 88 | ( 6.3) | 125 | 13.78 | 76 | ( 5.5) | 140 | 16.14 |
| Unlikely | | | | | | | | |
| <10 years | 428 | (56.1) | 1240 | 209.23 | 453 | (56.8) | 1307 | 214.97 |
| >=10 years | 848 | (60.3) | 2434 | 245.84 | 773 | (56.3) | 2254 | 238.73 |
| Missing | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 6 | ( 0.4) | 10 | 1.19 | 4 | ( 0.3) | 4 | 0.44 |
| Related to technical complaint for basal insulin | | | | | | | | |
| Yes | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.45 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 9 | ( 0.6) | 9 | 1.11 | 6 | ( 0.4) | 7 | 0.87 |
| No | | | | | | | | |
| <10 years | 443 | (58.1) | 1353 | 230.26 | 466 | (58.5) | 1396 | 229.69 |
| >=10 years | 882 | (62.7) | 2608 | 264.95 | 792 | (57.7) | 2466 | 261.38 |
| NA | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.12 |
| Missing | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 6 | ( 0.4) | 10 | 1.19 | 5 | ( 0.4) | 5 | 0.56 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Outcome | | | | | | | | |
| Fatal | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.63 | 5 | ( 0.6) | 5 | 0.80 |
| >=10 years | 11 | ( 0.8) | 15 | 1.48 | 8 | ( 0.6) | 10 | 0.82 |
| Not recovered/not resolved | | | | | | | | |
| <10 years | 193 | (25.3) | 339 | 56.10 | 215 | (27.0) | 391 | 62.68 |
| >=10 years | 396 | (28.1) | 748 | 73.69 | 355 | (25.9) | 651 | 66.90 |
| Recovered/resolved with sequelae | | | | | | | | |
| <10 years | 6 | ( 0.8) | 6 | 0.98 | 7 | ( 0.9) | 8 | 1.31 |
| >=10 years | 4 | ( 0.3) | 4 | 0.28 | 9 | ( 0.7) | 10 | 0.98 |
| Recovering/resolving | | | | | | | | |
| <10 years | 30 | ( 3.9) | 43 | 6.88 | 30 | ( 3.8) | 36 | 6.13 |
| >=10 years | 66 | ( 4.7) | 93 | 10.27 | 62 | ( 4.5) | 75 | 8.02 |
| Recovered/resolved | | | | | | | | |
| <10 years | 366 | (47.9) | 966 | 166.44 | 380 | (47.6) | 959 | 159.23 |
| >=10 years | 756 | (53.7) | 1767 | 181.59 | 659 | (48.0) | 1731 | 186.06 |
| Unknown | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.14 |
| Missing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

## 7.7.50 Adverse events by diabetes duration - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <10 years | 689 | | | | 714 | | | |
| >=10 years | 1191 | | | | 1164 | | | |
| PYE (years) | | | | | | | | |
| <10 years | 589.76 | | | | 616.53 | | | |
| >=10 years | 949.16 | | | | 919.93 | | | |
| Events | | | | | | | | |
| <10 years | 399 | (58.0) | 1222 | 216.31 | 416 | (58.2) | 1250 | 214.60 |
| >=10 years | 740 | (62.1) | 2256 | 251.73 | 657 | (56.5) | 2009 | 228.61 |
| Serious | | | | | | | | |
| Yes | | | | | | | | |
| <10 years | 43 | ( 6.2) | 62 | 10.67 | 53 | ( 7.3) | 69 | 11.86 |
| >=10 years | 112 | ( 9.4) | 168 | 18.11 | 109 | ( 9.4) | 160 | 16.68 |
| No | | | | | | | | |
| <10 years | 389 | (56.5) | 1160 | 205.64 | 406 | (56.8) | 1181 | 202.74 |
| >=10 years | 713 | (59.9) | 2088 | 233.62 | 630 | (54.2) | 1849 | 211.94 |
| Missing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Severity | | | | | | | | |
| Severe | | | | | | | | |
| <10 years | 21 | ( 3.0) | 28 | 5.13 | 29 | ( 4.0) | 37 | 6.38 |
| >=10 years | 62 | ( 5.2) | 83 | 9.29 | 56 | ( 4.8) | 91 | 8.91 |
| Moderate | | | | | | | | |
| <10 years | 160 | (23.2) | 288 | 50.61 | 164 | (22.9) | 305 | 49.99 |
| >=10 years | 301 | (25.2) | 553 | 58.82 | 263 | (22.7) | 462 | 51.76 |
| Mild | | | | | | | | |
| <10 years | 340 | (49.4) | 906 | 160.57 | 346 | (48.4) | 908 | 158.24 |
| >=10 years | 604 | (50.7) | 1620 | 183.62 | 557 | (47.9) | 1456 | 167.94 |
| Missing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Related to basal insulin | | | | | | | | |
| Probable | | | | | | | | |
| <10 years | 28 | ( 4.1) | 55 | 10.96 | 29 | ( 4.1) | 49 | 9.01 |
| >=10 years | 37 | ( 3.1) | 45 | 5.34 | 40 | ( 3.4) | 76 | 8.13 |
| Possible | | | | | | | | |
| <10 years | 33 | ( 4.8) | 47 | 9.00 | 25 | ( 3.5) | 34 | 5.67 |
| >=10 years | 70 | ( 5.9) | 106 | 13.00 | 63 | ( 5.4) | 103 | 12.61 |
| Unlikely | | | | | | | | |
| <10 years | 386 | (56.1) | 1118 | 195.98 | 402 | (56.2) | 1165 | 199.66 |
| >=10 years | 712 | (59.8) | 2095 | 231.98 | 635 | (54.6) | 1826 | 207.36 |
| Missing | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.37 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 6 | ( 0.5) | 10 | 1.41 | 4 | ( 0.3) | 4 | 0.52 |
| Related to technical complaint for basal insulin | | | | | | | | |
| Yes | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.50 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 9 | ( 0.8) | 9 | 1.31 | 6 | ( 0.5) | 7 | 1.02 |
| No | | | | | | | | |
| <10 years | 397 | (57.7) | 1218 | 215.45 | 415 | (58.1) | 1247 | 214.08 |
| >=10 years | 739 | (62.0) | 2236 | 248.87 | 653 | (56.2) | 1996 | 226.79 |
| NA | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| Missing | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.37 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 6 | ( 0.5) | 10 | 1.41 | 5 | ( 0.4) | 5 | 0.66 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Outcome | | | | | | | | |
| Fatal | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 5 | ( 0.7) | 5 | 0.89 |
| >=10 years | 11 | ( 0.9) | 15 | 1.74 | 8 | ( 0.7) | 10 | 0.97 |
| Not recovered/not resolved | | | | | | | | |
| <10 years | 173 | (25.1) | 314 | 54.87 | 196 | (27.4) | 352 | 58.88 |
| >=10 years | 330 | (27.6) | 639 | 68.26 | 291 | (25.1) | 546 | 60.71 |
| Recovered/resolved with sequelae | | | | | | | | |
| <10 years | 6 | ( 0.9) | 6 | 1.09 | 6 | ( 0.8) | 7 | 1.18 |
| >=10 years | 4 | ( 0.3) | 4 | 0.33 | 7 | ( 0.6) | 8 | 0.81 |
| Recovering/resolving | | | | | | | | |
| <10 years | 30 | ( 4.3) | 43 | 7.65 | 30 | ( 4.2) | 36 | 6.81 |
| >=10 years | 60 | ( 5.1) | 87 | 11.10 | 57 | ( 4.9) | 67 | 8.08 |
| Recovered/resolved | | | | | | | | |
| <10 years | 326 | (47.3) | 857 | 152.31 | 331 | (46.2) | 850 | 146.83 |
| >=10 years | 636 | (53.4) | 1510 | 170.22 | 547 | (47.1) | 1376 | 157.88 |
| Unknown | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.17 |
| Missing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

## 7.7.51 Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on- treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <10 years | 764 | | | | 796 | | | |
| >=10 years | 1406 | | | | 1374 | | | |
| PYE (years) | | | | | | | | |
| <10 years | 626.99 | | | | 656.89 | | | |
| >=10 years | 1054.24 | | | | 1023.69 | | | |
| Events | | | | | | | | |
| <10 years | 445 | (58.3) | 1357 | 231.03 | 467 | (58.6) | 1399 | 230.15 |
| >=10 years | 883 | (62.8) | 2628 | 267.37 | 796 | (58.0) | 2479 | 262.93 |
| Infections and infestations | | | | | | | | |
| All | | | | | | | | |
| <10 years | 217 | (28.4) | 323 | 55.70 | 222 | (27.7) | 349 | 56.04 |
| >=10 years | 431 | (30.6) | 597 | 62.76 | 402 | (29.4) | 556 | 58.98 |
| COVID-19 | | | | | | | | |
| <10 years | 65 | ( 8.6) | 67 | 11.02 | 70 | ( 8.7) | 73 | 11.90 |
| >=10 years | 116 | ( 8.2) | 118 | 12.43 | 122 | ( 9.0) | 126 | 12.48 |
| Nasopharyngitis | | | | | | | | |
| <10 years | 45 | ( 5.8) | 58 | 11.32 | 35 | ( 4.4) | 40 | 6.81 |
| >=10 years | 72 | ( 5.1) | 83 | 9.25 | 80 | ( 5.8) | 95 | 11.23 |
| Upper respiratory tract infection | | | | | | | | |
| <10 years | 25 | ( 3.3) | 32 | 4.88 | 19 | ( 2.4) | 21 | 3.35 |
| >=10 years | 43 | ( 3.1) | 49 | 4.91 | 33 | ( 2.4) | 35 | 3.67 |
| Urinary tract infection | | | | | | | | |
| <10 years | 12 | ( 1.5) | 12 | 2.11 | 17 | ( 2.1) | 19 | 3.10 |
| >=10 years | 31 | ( 2.2) | 34 | 3.54 | 33 | ( 2.4) | 37 | 3.61 |
| Gastroenteritis | | | | | | | | |
| <10 years | 11 | ( 1.5) | 11 | 1.94 | 8 | ( 1.0) | 8 | 1.31 |
| >=10 years | 21 | ( 1.5) | 22 | 2.77 | 10 | ( 0.7) | 11 | 1.36 |
| Bronchitis | | | | | | | | |
| <10 years | 12 | ( 1.6) | 12 | 2.18 | 9 | ( 1.1) | 9 | 1.40 |
| >=10 years | 18 | ( 1.3) | 19 | 1.98 | 10 | ( 0.7) | 10 | 1.08 |
| Influenza | | | | | | | | |
| <10 years | 12 | ( 1.6) | 13 | 2.63 | 13 | ( 1.6) | 14 | 2.70 |
| >=10 years | 17 | ( 1.2) | 19 | 2.19 | 20 | ( 1.4) | 22 | 2.66 |
| Sinusitis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.67 | 6 | ( 0.7) | 9 | 1.46 |
| >=10 years | 16 | ( 1.1) | 17 | 1.81 | 13 | ( 0.9) | 13 | 1.25 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| COVID-19 pneumonia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 5 | ( 0.6) | 5 | 0.82 |
| >=10 years | 13 | ( 0.9) | 13 | 1.31 | 6 | ( 0.4) | 6 | 0.55 |
| Pharyngitis | | | | | | | | |
| <10 years | 8 | ( 1.1) | 8 | 1.42 | 9 | ( 1.1) | 11 | 1.60 |
| >=10 years | 13 | ( 0.9) | 15 | 1.46 | 9 | ( 0.7) | 10 | 1.10 |
| Pneumonia | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.49 | 3 | ( 0.4) | 3 | 0.57 |
| >=10 years | 12 | ( 0.9) | 12 | 1.24 | 3 | ( 0.2) | 3 | 0.26 |
| Cystitis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.63 | 9 | ( 1.1) | 10 | 1.66 |
| >=10 years | 12 | ( 0.9) | 13 | 1.33 | 8 | ( 0.6) | 9 | 0.89 |
| Conjunctivitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 3 | ( 0.4) | 3 | 0.47 |
| >=10 years | 10 | ( 0.7) | 10 | 1.11 | 4 | ( 0.3) | 4 | 0.40 |
| Respiratory tract infection viral | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.88 | 4 | ( 0.5) | 4 | 0.82 |
| >=10 years | 9 | ( 0.6) | 9 | 1.05 | 6 | ( 0.4) | 7 | 0.85 |
| Herpes zoster | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.51 | 6 | ( 0.7) | 7 | 0.86 |
| >=10 years | 8 | ( 0.6) | 8 | 0.68 | 11 | ( 0.8) | 11 | 1.15 |
| Respiratory tract infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 3 | ( 0.4) | 3 | 0.47 |
| >=10 years | 7 | ( 0.5) | 7 | 0.72 | 3 | ( 0.2) | 3 | 0.28 |
| Rhinitis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.41 | 4 | ( 0.5) | 4 | 0.63 |
| >=10 years | 6 | ( 0.4) | 6 | 0.62 | 7 | ( 0.5) | 10 | 1.27 |
| Otitis media | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.33 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 5 | ( 0.4) | 5 | 0.56 | 4 | ( 0.3) | 4 | 0.46 |
| Vaginal infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 5 | ( 0.4) | 6 | 0.67 | 1 | ( 0.1) | 1 | 0.12 |
| Tooth infection | | | | | | | | |
| <10 years | 4 | ( 0.5) | 6 | 0.90 | 3 | ( 0.4) | 3 | 0.60 |
| >=10 years | 5 | ( 0.4) | 5 | 0.53 | 5 | ( 0.4) | 5 | 0.57 |
| Viral infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 7 | ( 0.9) | 10 | 1.45 |
| >=10 years | 5 | ( 0.4) | 5 | 0.53 | 6 | ( 0.4) | 6 | 0.66 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Periodontitis | | | | | | | | |
| <10 years | 0 | | | | 4 | ( 0.5) | 4 | 0.60 |
| >=10 years | 5 | ( 0.4) | 5 | 0.53 | 3 | ( 0.2) | 3 | 0.39 |
| Tooth abscess | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.82 | 3 | ( 0.4) | 3 | 0.36 |
| >=10 years | 5 | ( 0.4) | 5 | 0.53 | 4 | ( 0.3) | 5 | 0.53 |
| Fungal infection | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.49 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 5 | 0.51 | 2 | ( 0.1) | 2 | 0.20 |
| Lower respiratory tract infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 4 | ( 0.3) | 4 | 0.36 | 2 | ( 0.1) | 4 | 0.30 |
| Cellulitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 5 | ( 0.6) | 6 | 1.28 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 3 | ( 0.2) | 3 | 0.22 |
| Ear infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 3 | ( 0.2) | 3 | 0.32 |
| Acute sinusitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 3 | ( 0.4) | 3 | 0.62 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 3 | ( 0.2) | 3 | 0.34 |
| Gastroenteritis viral | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.54 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 4 | ( 0.3) | 4 | 0.49 |
| Localised infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 2 | ( 0.1) | 2 | 0.27 |
| Gingivitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 3 | ( 0.2) | 4 | 0.36 | 4 | ( 0.3) | 4 | 0.44 |
| Coronavirus infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 4 | ( 0.5) | 5 | 0.75 |
| >=10 years | 3 | ( 0.2) | 3 | 0.21 | 1 | ( 0.1) | 2 | 0.25 |
| Vulvitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 0 | | | |
| Helicobacter infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 2 | ( 0.1) | 2 | 0.20 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Oral herpes | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 2 | ( 0.1) | 3 | 0.37 | 0 | | | |
| Onychomycosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 2 | ( 0.1) | 2 | 0.20 | 2 | ( 0.1) | 2 | 0.14 |
| Otitis externa | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 5 | ( 0.4) | 5 | 0.59 |
| Wound infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.12 |
| Tinea cruris | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.21 | 0 | | | |
| Abscess | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Osteomyelitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Vulvovaginal mycotic infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Hordeolum | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 3 | ( 0.2) | 3 | 0.39 |
| Enteritis infectious | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Kidney infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Pustule | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Subcutaneous abscess | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 2 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Tonsillitis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.53 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.12 |
| Varicella zoster virus infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Escherichia bacteraemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Furuncle | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.27 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Genital candidiasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Injection site abscess | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Postoperative wound infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |
| Skin infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.47 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.15 |
| Suspected COVID-19 | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Tinea pedis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.27 |
| Bacteraemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Cholecystitis infective | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |
| Diabetic foot infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Infected dermal cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Paronychia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 3 | 0.37 |
| Pharyngotonsillitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 2 | 0.15 |
| Pneumonia viral | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Pulmonary tuberculoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Respiratory syncytial virus infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Sepsis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Viral tracheitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Abscess limb | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.1) | 3 | 0.42 |
| Eye infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.1) | 2 | 0.25 |
| Gastrointestinal infection | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.42 | 3 | ( 0.4) | 4 | 0.48 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.1) | 3 | 0.44 |
| Genital infection fungal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.08 |
| Norovirus infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Severe acute respiratory syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |
| Clostridium difficile colitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Clostridium difficile infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Erysipelas | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 1 | ( 0.1) | 2 | 0.44 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Fungal skin infection | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.46 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.13 |
| Gangrene | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Genital infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.35 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Nail infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.08 |
| Peritonsillar abscess | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.12 |
| Pyelonephritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Viral pharyngitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Asymptomatic COVID-19 | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.20 |
| Balanitis candida | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Candida infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.13 |
| Chlamydial infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Chronic tonsillitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Dermatophytosis of nail | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Helicobacter gastritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Herpes virus infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Infected bite | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Laryngitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 2 | ( 0.3) | 2 | 0.45 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 3 | ( 0.2) | 3 | 0.30 |
| Mastitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Oropharyngeal candidiasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Otitis media chronic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Pericoronitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Purulence | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Abdominal abscess | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Acarodermatitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 3 | ( 0.2) | 3 | 0.22 |
| Anal abscess | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Appendicitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Bacterial infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Bartholinitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Body tinea | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Breast abscess | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Breast cellulitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Campylobacter gastroenteritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Chronic hepatitis C | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Chronic sinusitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Cystitis escherichia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Diverticulitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 5 | ( 0.4) | 5 | 0.37 |
| Ear infection fungal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Empyema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Endophthalmitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Epididymitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Escherichia urinary tract infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Eye infection bacterial | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Folliculitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Fungal balanitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Gastric infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Gastroenteritis norovirus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Giardiasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Herpes dermatitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Herpes simplex | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Herpes zoster infection neurological | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Infected cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Infective iritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Labyrinthitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Laryngopharyngitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 2 | 0.24 |
| >=10 years | 0 | | | | 0 | | | |
| Lyme disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Oophoritis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Oral candidiasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Otitis media acute | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Paraspinal abscess | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Parotitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Peri-implantitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Post procedural infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Post-acute COVID-19 syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pulpitis dental | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 3 | ( 0.2) | 3 | 0.37 |
| Rotavirus infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Salpingitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Sinusitis bacterial | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Skin bacterial infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Skin candida | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Soft tissue infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Sweat gland infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Tinea infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Tinea versicolour | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Tracheitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Urethritis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Urosepsis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Varicella | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Viral rhinitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Viral upper respiratory tract infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |
| Vulvovaginal candidiasis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.60 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |
| Vulvovaginitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gastrointestinal disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 88 | (11.5) | 135 | 21.93 | 90 | (11.3) | 126 | 21.10 |
| >=10 years | 189 | (13.4) | 283 | 28.07 | 155 | (11.3) | 217 | 22.58 |
| Diarrhoea | | | | | | | | |
| <10 years | 20 | ( 2.6) | 24 | 3.91 | 21 | ( 2.6) | 21 | 3.68 |
| >=10 years | 69 | ( 4.9) | 84 | 8.14 | 34 | ( 2.5) | 36 | 3.73 |
| Nausea | | | | | | | | |
| <10 years | 14 | ( 1.9) | 15 | 2.43 | 14 | ( 1.8) | 14 | 2.52 |
| >=10 years | 27 | ( 1.9) | 27 | 2.71 | 21 | ( 1.5) | 23 | 2.46 |
| Vomiting | | | | | | | | |
| <10 years | 10 | ( 1.3) | 13 | 2.64 | 7 | ( 0.9) | 8 | 1.33 |
| >=10 years | 21 | ( 1.5) | 26 | 2.90 | 14 | ( 1.0) | 16 | 1.68 |
| Constipation | | | | | | | | |
| <10 years | 6 | ( 0.8) | 6 | 1.00 | 5 | ( 0.6) | 5 | 1.11 |
| >=10 years | 11 | ( 0.8) | 14 | 1.49 | 11 | ( 0.8) | 11 | 1.01 |
| Abdominal pain upper | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.87 | 8 | ( 1.0) | 9 | 1.35 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 11 | ( 0.8) | 13 | 1.33 | 8 | ( 0.6) | 8 | 0.78 |
| Abdominal pain | | | | | | | | |
| <10 years | 6 | ( 0.8) | 6 | 1.08 | 8 | ( 1.0) | 8 | 1.09 |
| >=10 years | 11 | ( 0.8) | 11 | 0.98 | 10 | ( 0.7) | 11 | 1.21 |
| Gastrooesophageal reflux disease | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.49 | 4 | ( 0.5) | 4 | 0.50 |
| >=10 years | 11 | ( 0.8) | 11 | 1.00 | 11 | ( 0.8) | 11 | 1.18 |
| Dental caries | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.52 | 4 | ( 0.5) | 4 | 0.48 |
| >=10 years | 8 | ( 0.6) | 10 | 0.77 | 6 | ( 0.4) | 6 | 0.74 |
| Chronic gastritis | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.32 | 3 | ( 0.4) | 3 | 0.60 |
| >=10 years | 7 | ( 0.5) | 7 | 0.73 | 3 | ( 0.2) | 3 | 0.30 |
| Toothache | | | | | | | | |
| <10 years | 8 | ( 1.1) | 8 | 1.21 | 5 | ( 0.6) | 6 | 1.27 |
| >=10 years | 7 | ( 0.5) | 7 | 0.67 | 8 | ( 0.6) | 12 | 1.52 |
| Dyspepsia | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.55 | 3 | ( 0.4) | 3 | 0.46 |
| >=10 years | 5 | ( 0.4) | 5 | 0.53 | 6 | ( 0.4) | 6 | 0.61 |
| Gastritis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.57 | 3 | ( 0.4) | 3 | 0.58 |
| >=10 years | 5 | ( 0.4) | 5 | 0.53 | 6 | ( 0.4) | 6 | 0.53 |
| Large intestine polyp | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 4 | ( 0.3) | 4 | 0.33 | 4 | ( 0.3) | 5 | 0.42 |
| Abdominal distension | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.53 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 4 | ( 0.3) | 4 | 0.41 | 4 | ( 0.3) | 4 | 0.47 |
| Food poisoning | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 4 | ( 0.3) | 5 | 0.57 |
| Flatulence | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 2 | ( 0.1) | 2 | 0.25 |
| Abdominal discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.2) | 3 | 0.70 |
| >=10 years | 3 | ( 0.2) | 3 | 0.34 | 4 | ( 0.3) | 4 | 0.34 |
| Diverticulum intestinal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 3 | ( 0.2) | 3 | 0.28 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Abdominal pain lower | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.07 |
| Hiatus hernia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 2 | ( 0.1) | 2 | 0.22 |
| Hypoaesthesia oral | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 4 | 0.49 | 0 | | | |
| Pancreatic failure | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 0 | | | |
| Haemorrhoids | | | | | | | | |
| <10 years | 5 | ( 0.6) | 5 | 0.72 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 3 | ( 0.2) | 3 | 0.39 |
| Impaired gastric emptying | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 3 | 0.36 | 0 | | | |
| Aphthous ulcer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Dry mouth | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.08 |
| Gingival bleeding | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Intra-abdominal haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.08 |
| Tongue rough | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Noninfective gingivitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Oral pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Pancreatic duct dilatation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Pancreatitis chronic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.08 |
| Proctalgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Faeces soft | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Irritable bowel syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Abdominal wall disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Diabetic gastropathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Eosinophilic oesophagitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Eructation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Gastrointestinal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Haemorrhoidal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Inguinal hernia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 2 | 0.15 |
| Intestinal dilatation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Colitis ischaemic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Enterocolitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.41 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Frequent bowel movements | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Haematochezia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Hyperaesthesia teeth | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Pancreatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Acid peptic disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |
| Anal fissure | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Anal pruritus | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Colitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Colitis microscopic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Crohn's disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Diverticulum | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.20 |
| Duodenitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Enteritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Epigastric discomfort | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Faeces pale | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Gastric dilatation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gastric disorder | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Gastric dysplasia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Gastric mucosal hypertrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=10 years | 0 | | | | 0 | | | |
| Gastric polyps | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 2 | ( 0.3) | 2 | 0.49 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.22 |
| Gastric ulcer | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gastritis erosive | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.29 |
| Gastrointestinal angiodysplasia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gastrointestinal disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Gastrointestinal inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Gastrointestinal sounds abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gingival disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Gingival recession | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.29 |
| Hyperchlorhydria | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Ileus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Lip swelling | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Loose tooth | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Lumbar hernia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Melaena | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Mesenteric panniculitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Odynophagia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Oesophageal pain | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Oesophagitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Oral discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pancreatic pseudocyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Pancreatitis acute | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Peptic ulcer | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Periodontal disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Periodontal inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.15 |
| Pneumatosis intestinalis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Rectal polyp | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Rectal prolapse | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Small intestinal obstruction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Stomatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Tooth disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Tooth impacted | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Ulcerative gastritis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Umbilical hernia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Upper gastrointestinal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Vomiting projectile | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 84 | (11.0) | 117 | 18.86 | 104 | (13.1) | 142 | 24.05 |
| >=10 years | 189 | (13.4) | 283 | 27.54 | 180 | (13.1) | 259 | 27.09 |
| Back pain | | | | | | | | |
| <10 years | 21 | ( 2.7) | 21 | 3.78 | 17 | ( 2.1) | 19 | 3.43 |
| >=10 years | 44 | ( 3.1) | 48 | 4.33 | 55 | ( 4.0) | 70 | 8.00 |
| Arthralgia | | | | | | | | |
| <10 years | 17 | ( 2.2) | 20 | 3.35 | 21 | ( 2.7) | 23 | 4.32 |
| >=10 years | 34 | ( 2.4) | 39 | 3.86 | 36 | ( 2.6) | 40 | 4.11 |
| Pain in extremity | | | | | | | | |
| <10 years | 11 | ( 1.4) | 12 | 1.78 | 9 | ( 1.1) | 10 | 1.97 |
| >=10 years | 26 | ( 1.8) | 27 | 2.58 | 28 | ( 2.0) | 33 | 3.44 |
| Muscle spasms | | | | | | | | |
| <10 years | 5 | ( 0.6) | 5 | 0.81 | 3 | ( 0.4) | 3 | 0.38 |
| >=10 years | 20 | ( 1.4) | 22 | 2.35 | 6 | ( 0.4) | 6 | 0.59 |
| Osteoarthritis | | | | | | | | |
| <10 years | 6 | ( 0.8) | 7 | 1.21 | 10 | ( 1.2) | 11 | 1.66 |
| >=10 years | 18 | ( 1.3) | 19 | 1.78 | 16 | ( 1.2) | 18 | 1.82 |
| Myalgia | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.72 | 6 | ( 0.7) | 7 | 1.44 |
| >=10 years | 12 | ( 0.9) | 12 | 1.31 | 10 | ( 0.7) | 10 | 1.25 |
| Neck pain | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.67 | 4 | ( 0.5) | 4 | 0.60 |
| >=10 years | 12 | ( 0.9) | 12 | 1.22 | 4 | ( 0.3) | 4 | 0.35 |
| Trigger finger | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 3 | ( 0.4) | 5 | 0.74 |
| >=10 years | 8 | ( 0.6) | 8 | 0.98 | 3 | ( 0.2) | 3 | 0.29 |
| Tendonitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 6 | ( 0.4) | 8 | 0.77 | 4 | ( 0.3) | 4 | 0.42 |
| Periarthritis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 4 | ( 0.5) | 4 | 0.60 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 6 | ( 0.4) | 6 | 0.53 | 5 | ( 0.4) | 5 | 0.59 |
| Rotator cuff syndrome | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.36 |
| >=10 years | 5 | ( 0.4) | 5 | 0.46 | 1 | ( 0.1) | 1 | 0.07 |
| Intervertebral disc protrusion | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.46 | 3 | ( 0.4) | 4 | 0.60 |
| >=10 years | 5 | ( 0.3) | 9 | 0.68 | 3 | ( 0.2) | 3 | 0.27 |
| Spinal stenosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 4 | ( 0.3) | 6 | 0.64 | 0 | | | |
| Muscular weakness | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 2 | ( 0.1) | 2 | 0.20 |
| Spinal osteoarthritis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 3 | ( 0.2) | 4 | 0.28 |
| Arthritis | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.61 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 3 | ( 0.2) | 3 | 0.34 | 4 | ( 0.3) | 4 | 0.44 |
| Musculoskeletal chest pain | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.21 | 1 | ( 0.1) | 1 | 0.07 |
| Osteoporosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 0 | | | |
| Musculoskeletal stiffness | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.54 | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 0 | | | |
| Tendon disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.13 |
| Foot deformity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 3 | 0.26 | 2 | ( 0.1) | 2 | 0.19 |
| Osteochondrosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 2 | ( 0.1) | 2 | 0.25 |
| Synovial cyst | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.22 | 1 | ( 0.1) | 1 | 0.07 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Bursitis | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.32 | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.15 |
| Chondropathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Groin pain | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.08 |
| Plantar fasciitis | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.33 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 3 | 0.21 | 2 | ( 0.1) | 2 | 0.15 |
| Axillary mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.08 |
| Flank pain | | | | | | | | |
| <10 years | 0 | | | | 4 | ( 0.5) | 5 | 0.83 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.20 |
| Polymyalgia rheumatica | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 3 | 0.36 |
| Soft tissue swelling | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 3 | 0.37 | 0 | | | |
| Joint effusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.24 | 2 | ( 0.1) | 2 | 0.15 |
| Muscle contracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.08 |
| Pain in jaw | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Torticollis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.13 |
| Back disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Coccydynia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |
| Limb discomfort | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Tenosynovitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 6 | ( 0.7) | 7 | 0.96 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 3 | ( 0.2) | 3 | 0.27 |
| Acquired claw toe | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Meniscopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Polyarthritis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Exostosis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Fibromyalgia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Fistula | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Intervertebral disc disorder | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.33 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.12 |
| Lumbar spinal stenosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Myositis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.13 |
| Osteopenia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Spinal pain | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.15 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Arthropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Bone cyst | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Bone pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Cervical spinal stenosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Chondromalacia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Costochondritis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Diastasis recti abdominis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Dupuytren's contracture | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Facet joint syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Haemarthrosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Intervertebral disc degeneration | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Intervertebral disc space narrowing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.14 |
| Jaw disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Joint swelling | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.44 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Limb deformity | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Limb mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Mastication disorder | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Muscle twitching | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Musculoskeletal pain | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Neuropathic arthropathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Nodal osteoarthritis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Osteochondritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Periostitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Psoriatic arthropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Rheumatoid arthritis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.27 |
| Sacroiliitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Scoliosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Spinal retrolisthesis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.14 |
| Tenosynovitis stenosans | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Vertebral osteophyte | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| General disorders and administration site conditions | | | | | | | | |
| All | | | | | | | | |
| <10 years | 80 | (10.5) | 135 | 23.74 | 78 | ( 9.7) | 113 | 19.47 |
| >=10 years | 160 | (11.4) | 228 | 24.71 | 130 | ( 9.5) | 231 | 24.59 |
| Pyrexia | | | | | | | | |
| <10 years | 9 | ( 1.2) | 10 | 1.56 | 16 | ( 2.0) | 17 | 2.99 |
| >=10 years | 32 | ( 2.3) | 33 | 3.56 | 27 | ( 2.0) | 28 | 2.81 |
| Fatigue | | | | | | | | |
| <10 years | 14 | ( 1.9) | 15 | 2.50 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 18 | ( 1.3) | 21 | 2.23 | 14 | ( 1.0) | 14 | 1.29 |
| Oedema peripheral | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.77 | 3 | ( 0.4) | 3 | 0.47 |
| >=10 years | 15 | ( 1.1) | 15 | 1.46 | 7 | ( 0.5) | 8 | 0.72 |
| Chest pain | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 3 | ( 0.4) | 3 | 0.49 |
| >=10 years | 12 | ( 0.8) | 12 | 1.10 | 4 | ( 0.3) | 4 | 0.36 |
| Injection site reaction | | | | | | | | |
| <10 years | 5 | ( 0.6) | 14 | 3.04 | 0 | | | |
| >=10 years | 10 | ( 0.7) | 15 | 1.79 | 6 | ( 0.4) | 8 | 0.73 |
| Malaise | | | | | | | | |
| <10 years | 6 | ( 0.8) | 8 | 1.19 | 3 | ( 0.4) | 7 | 1.37 |
| >=10 years | 10 | ( 0.7) | 10 | 1.06 | 12 | ( 0.9) | 53 | 7.11 |
| Pain | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.83 | 6 | ( 0.8) | 7 | 1.38 |
| >=10 years | 9 | ( 0.6) | 10 | 1.12 | 8 | ( 0.6) | 8 | 0.64 |
| Vaccination site pain | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 8 | ( 0.6) | 10 | 1.08 | 7 | ( 0.5) | 7 | 0.79 |
| Influenza like illness | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 2 | ( 0.3) | 2 | 0.24 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 6 | ( 0.4) | 7 | 0.80 | 2 | ( 0.1) | 2 | 0.22 |
| Medical device site reaction | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 6 | ( 0.4) | 8 | 0.87 | 0 | | | |
| Chest discomfort | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.46 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.51 | 2 | ( 0.1) | 2 | 0.20 |
| Medical device site dermatitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 5 | 0.81 | 5 | ( 0.6) | 11 | 1.50 |
| >=10 years | 5 | ( 0.4) | 5 | 0.61 | 6 | ( 0.4) | 7 | 0.74 |
| Medical device site rash | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 5 | ( 0.6) | 5 | 1.24 |
| >=10 years | 5 | ( 0.4) | 5 | 0.73 | 3 | ( 0.2) | 3 | 0.44 |
| Asthenia | | | | | | | | |
| <10 years | 5 | ( 0.6) | 5 | 0.83 | 3 | ( 0.4) | 3 | 0.59 |
| >=10 years | 5 | ( 0.4) | 5 | 0.51 | 7 | ( 0.5) | 7 | 0.72 |
| Medical device site bruise | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.54 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 4 | ( 0.3) | 5 | 0.61 | 0 | | | |
| Hunger | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.54 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.41 | 3 | ( 0.2) | 4 | 0.49 |
| Injection site pain | | | | | | | | |
| <10 years | 0 | | | | 6 | ( 0.8) | 6 | 1.16 |
| >=10 years | 3 | ( 0.2) | 3 | 0.37 | 7 | ( 0.5) | 25 | 1.99 |
| Injection site bruising | | | | | | | | |
| <10 years | 0 | | | | 5 | ( 0.6) | 5 | 0.71 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 0 | | | |
| Medical device site pruritus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 3 | ( 0.4) | 3 | 0.62 |
| >=10 years | 3 | ( 0.2) | 3 | 0.34 | 1 | ( 0.1) | 1 | 0.15 |
| Medical device site erythema | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 3 | ( 0.2) | 4 | 0.57 |
| Injection site erythema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 4 | 0.49 | 4 | ( 0.3) | 4 | 0.30 |
| Injection site haematoma | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 8 | 1.78 |
| >=10 years | 2 | ( 0.1) | 6 | 0.73 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 2 | ( 0.1) | 2 | 0.20 |
| Feeling abnormal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 3 | 0.41 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 0 | | | |
| Injection site pruritus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 17 | 3.79 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Drug intolerance | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Gait disturbance | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.07 |
| Medical device site haemorrhage | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.22 |
| Application site pruritus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 8 | 1.00 |
| Injection site haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.12 |
| Injection site rash | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Injection site swelling | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.12 |
| Peripheral swelling | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.53 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 1 | ( 0.1) | 2 | 0.24 | 2 | ( 0.1) | 2 | 0.25 |
| Multiple organ dysfunction syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 3 | ( 0.2) | 3 | 0.27 |
| Oedema due to renal disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Vaccination site inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Vaccination site pruritus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Medical device site haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Medical device site irritation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Medical device site pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 3 | 0.60 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Swelling face | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.1) | 2 | 0.19 |
| Early satiety | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Vessel puncture site bruise | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Chills | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.46 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Implant site pruritus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Injection site hypersensitivity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Injection site mass | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.15 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Medical device site eczema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Swelling | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Vaccination site reaction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Application site bruise | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Axillary pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Condition aggravated | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.20 |
| Death | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |
| Facial pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Feeling hot | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Hernia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Hyperthermia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Injection site dermatitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Injection site hypertrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Injection site induration | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.34 |
| >=10 years | 0 | | | | 0 | | | |
| Injection site oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Injection site urticaria | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.54 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Localised oedema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Medical device site hypersensitivity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Medical device site inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Non-cardiac chest pain | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 4 | 0.48 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.14 |
| Procedural failure | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Systemic inflammatory response syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Thirst | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.59 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Vaccination site erythema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Xerosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

Injury, poisoning and procedural complications

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| All | | | | | | | | |
| <10 years | 58 | ( 7.6) | 73 | 12.68 | 66 | ( 8.3) | 82 | 14.52 |
| >=10 years | 136 | ( 9.7) | 168 | 17.36 | 114 | ( 8.3) | 135 | 14.84 |
| Fall | | | | | | | | |
| <10 years | 5 | ( 0.6) | 5 | 0.71 | 3 | ( 0.4) | 4 | 0.59 |
| >=10 years | 15 | ( 1.1) | 15 | 1.39 | 8 | ( 0.6) | 8 | 0.80 |
| Vaccination complication | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.90 | 14 | ( 1.7) | 20 | 3.47 |
| >=10 years | 15 | ( 1.1) | 19 | 2.07 | 15 | ( 1.1) | 18 | 1.98 |
| Accidental overdose | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.46 | 2 | ( 0.3) | 3 | 0.67 |
| >=10 years | 12 | ( 0.9) | 13 | 1.66 | 2 | ( 0.1) | 2 | 0.27 |
| Contusion | | | | | | | | |
| <10 years | 5 | ( 0.6) | 5 | 0.80 | 3 | ( 0.4) | 3 | 0.38 |
| >=10 years | 10 | ( 0.7) | 11 | 1.01 | 6 | ( 0.4) | 6 | 0.64 |
| Ligament sprain | | | | | | | | |
| <10 years | 5 | ( 0.6) | 5 | 0.95 | 3 | ( 0.4) | 3 | 0.57 |
| >=10 years | 7 | ( 0.5) | 7 | 0.80 | 5 | ( 0.4) | 5 | 0.51 |
| Skin laceration | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 6 | ( 0.4) | 6 | 0.58 | 0 | | | |
| Skin abrasion | | | | | | | | |
| <10 years | 4 | ( 0.5) | 7 | 1.19 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.57 | 5 | ( 0.4) | 5 | 0.59 |
| Incorrect dose administered | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 2 | ( 0.3) | 2 | 0.34 |
| >=10 years | 5 | ( 0.4) | 5 | 0.66 | 3 | ( 0.2) | 5 | 0.62 |
| Hand fracture | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.46 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.45 | 1 | ( 0.1) | 1 | 0.07 |
| Overdose | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.57 |
| >=10 years | 4 | ( 0.3) | 4 | 0.44 | 0 | | | |
| Road traffic accident | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.54 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.38 | 1 | ( 0.1) | 1 | 0.07 |
| Prescribed overdose | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.58 | 0 | | | |
| Rib fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.2) | 2 | 0.25 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 3 | ( 0.2) | 3 | 0.32 |
| Arthropod bite | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.36 |
| >=10 years | 3 | ( 0.2) | 3 | 0.37 | 2 | ( 0.1) | 2 | 0.27 |
| Joint injury | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 4 | ( 0.3) | 4 | 0.41 |
| Procedural pain | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 1 | ( 0.1) | 1 | 0.12 |
| Limb injury | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.63 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 5 | ( 0.4) | 6 | 0.63 |
| Wound | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.46 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 4 | ( 0.3) | 4 | 0.47 |
| Face injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.15 |
| Medication error | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.24 | 2 | ( 0.1) | 2 | 0.27 |
| Tendon rupture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.12 |
| Foot fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 3 | ( 0.4) | 3 | 0.49 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 0 | | | |
| Tooth fracture | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.13 |
| Arthropod sting | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.12 |
| Back injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.22 |
| Upper limb fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Ankle fracture | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 3 | ( 0.2) | 3 | 0.21 |
| Hip fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Craniocerebral injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Subcutaneous haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.13 |
| Thermal burn | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.13 |
| Underdose | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.59 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.24 |
| Wrist fracture | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Accidental underdose | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Chillblains | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Extra dose administered | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.12 |
| Subdural haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Wrong product administered | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.50 |
| >=10 years | 1 | ( 0.1) | 2 | 0.25 | 4 | ( 0.3) | 4 | 0.54 |
| Epicondylitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.07 |
| Product dispensing error | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Bone contusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.20 |
| Inflammation of wound | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Injury of conjunctiva | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Multiple injuries | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Muscle injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.25 |
| Neck injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Post procedural complication | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Post procedural haematuria | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Post procedural inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Radiation skin injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Cervical vertebral fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Eye injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Fibula fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Heat illness | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 3 | 0.49 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Injury | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Meniscus injury | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 3 | 0.46 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.14 |
| Post procedural haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Post procedural hypothyroidism | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Traumatic haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Anaemia postoperative | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Animal bite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 3 | ( 0.2) | 3 | 0.27 |
| Animal scratch | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Burn oral cavity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Burns first degree | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Clavicle fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Concussion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Corneal abrasion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Crush injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Deafness traumatic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Endotracheal intubation complication | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Exposure to SARS-CoV-2 | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Facial bones fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Femoral neck fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gun shot wound | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Head injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Heat stroke | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Humerus fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Intentional overdose | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Intentional product use issue | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Ligament rupture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.45 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lower limb fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Muscle contusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Muscle strain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 5 | ( 0.4) | 5 | 0.54 |
| Nerve injury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Penile contusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Periprocedural myocardial infarction | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Post procedural fistula | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Post procedural stroke | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Post procedural swelling | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Post-traumatic neck syndrome | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Procedural complication | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Product administration error | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Radius fracture | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Scar | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Scratch | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Seroma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Soft tissue injury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Spinal column injury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Spinal compression fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Stab wound | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Sunburn | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Tendon injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Tibia fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Wound dehiscence | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Wrong dose | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Eye disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 44 | ( 5.7) | 52 | 9.24 | 51 | ( 6.4) | 63 | 10.66 |
| >=10 years | 132 | ( 9.4) | 173 | 18.51 | 129 | ( 9.4) | 173 | 19.53 |
| Diabetic retinopathy | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 19 | ( 2.4) | 21 | 3.92 | 17 | ( 2.2) | 18 | 3.39 |
| >=10 years | 45 | ( 3.2) | 49 | 5.77 | 55 | ( 4.0) | 58 | 6.63 |
| Cataract | | | | | | | | |
| <10 years | 6 | ( 0.8) | 7 | 1.24 | 6 | ( 0.7) | 6 | 0.72 |
| >=10 years | 22 | ( 1.6) | 26 | 2.36 | 21 | ( 1.5) | 24 | 2.45 |
| Macular oedema | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.58 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 9 | ( 0.6) | 10 | 1.22 | 4 | ( 0.3) | 4 | 0.42 |
| Retinopathy hypertensive | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 8 | ( 0.6) | 9 | 0.99 | 4 | ( 0.3) | 4 | 0.50 |
| Dry eye | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 5 | ( 0.6) | 5 | 0.85 |
| >=10 years | 5 | ( 0.4) | 5 | 0.48 | 2 | ( 0.1) | 2 | 0.15 |
| Diabetic retinal oedema | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.43 | 3 | ( 0.4) | 3 | 0.36 |
| >=10 years | 4 | ( 0.3) | 4 | 0.54 | 7 | ( 0.5) | 8 | 0.96 |
| Blepharitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.28 | 0 | | | |
| Retinal haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.37 | 0 | | | |
| Non-proliferative retinopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 3 | ( 0.2) | 4 | 0.54 | 4 | ( 0.3) | 4 | 0.54 |
| Vision blurred | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.49 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 3 | ( 0.2) | 3 | 0.41 | 3 | ( 0.2) | 3 | 0.32 |
| Eye pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 1 | ( 0.1) | 1 | 0.08 |
| Vitreous detachment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 2 | ( 0.1) | 2 | 0.29 |
| Glaucoma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 3 | ( 0.2) | 3 | 0.20 | 5 | ( 0.4) | 5 | 0.64 |
| Ocular hyperaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.44 |
| >=10 years | 2 | ( 0.1) | 3 | 0.37 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vitreous haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 2 | ( 0.1) | 2 | 0.20 |
| Conjunctival haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 0 | | | |
| Epiretinal membrane | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 2 | ( 0.1) | 2 | 0.19 |
| Eye inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.13 |
| Age-related macular degeneration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Arteriosclerotic retinopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.21 | 0 | | | |
| Posterior capsule opacification | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.22 | 0 | | | |
| Dry age-related macular degeneration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Eye irritation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Lacrimation increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Myopia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.22 |
| Retinal exudates | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.25 |
| Diplopia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Presbyopia | | | | | | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 3 | ( 0.2) | 3 | 0.39 |
| Retinal deposits | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Retinal drusen | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.13 |
| Retinal scar | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Cataract nuclear | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Corneal erosion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.13 |
| Retinal vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.13 |
| Amaurosis fugax | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Angle closure glaucoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Conjunctival hyperaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Maculopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Ocular hypertension | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 2 | 0.29 |
| Visual impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 10 | 1.20 |
| Vitreous opacities | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Acquired epiblepharon | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Asthenopia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Astigmatism | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.25 | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 3 | ( 0.2) | 3 | 0.39 |
| Conjunctival erosion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Conjunctivitis allergic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Optic disc vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Post thrombotic retinopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Retinal aneurysm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Retinal tear | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Chorioretinal atrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Conjunctival suffusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Corneal bleeding | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Cystoid macular oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Dacryoadenitis acquired | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Eye discharge | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Eye pruritus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.44 |
| >=10 years | 0 | | | | 0 | | | |
| Eyelid oedema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Hypermetropia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Macular degeneration | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.20 |
| Macular hole | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Meibomianitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Normal tension glaucoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Ocular ischaemic syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Open angle glaucoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.25 |
| Ophthalmic vein thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Optic disc haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Photophobia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Photopsia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Pterygium | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Retinal artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Retinal degeneration | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Retinal detachment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.20 |
| Retinal vein occlusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Retinopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Scintillating scotoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Uveitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Visual acuity reduced | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Vitreous degeneration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Vitreous floaters | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 3 | ( 0.2) | 3 | 0.42 |
| Nervous system disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 79 | (10.3) | 120 | 22.64 | 76 | ( 9.5) | 99 | 16.01 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 128 | ( 9.1) | 178 | 17.98 | 131 | ( 9.5) | 227 | 26.21 |
| Headache | | | | | | | | |
| <10 years | 30 | ( 3.9) | 41 | 7.86 | 27 | ( 3.4) | 37 | 6.10 |
| >=10 years | 40 | ( 2.9) | 51 | 5.81 | 37 | ( 2.7) | 43 | 4.82 |
| Dizziness | | | | | | | | |
| <10 years | 18 | ( 2.4) | 24 | 4.11 | 12 | ( 1.5) | 15 | 2.54 |
| >=10 years | 22 | ( 1.6) | 27 | 2.71 | 27 | ( 2.0) | 32 | 3.41 |
| Sciatica | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.48 | 6 | ( 0.8) | 6 | 0.86 |
| >=10 years | 10 | ( 0.7) | 10 | 1.02 | 6 | ( 0.4) | 7 | 0.67 |
| Carpal tunnel syndrome | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.58 | 0 | | | |
| >=10 years | 8 | ( 0.6) | 8 | 0.67 | 8 | ( 0.6) | 8 | 0.87 |
| Tremor | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.80 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 7 | ( 0.5) | 8 | 0.66 | 9 | ( 0.7) | 60 | 8.49 |
| Hypoaesthesia | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.58 | 4 | ( 0.5) | 5 | 0.72 |
| >=10 years | 6 | ( 0.4) | 9 | 0.79 | 6 | ( 0.4) | 6 | 0.66 |
| Syncope | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 5 | ( 0.4) | 5 | 0.48 | 0 | | | |
| Diabetic neuropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 3 | ( 0.4) | 3 | 0.47 |
| >=10 years | 5 | ( 0.4) | 5 | 0.53 | 9 | ( 0.7) | 9 | 0.91 |
| Neuropathy peripheral | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.58 | 3 | ( 0.4) | 3 | 0.49 |
| >=10 years | 4 | ( 0.3) | 4 | 0.38 | 7 | ( 0.5) | 7 | 0.68 |
| Tension headache | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 3 | ( 0.2) | 4 | 0.34 | 0 | | | |
| Migraine | | | | | | | | |
| <10 years | 5 | ( 0.6) | 6 | 1.28 | 3 | ( 0.4) | 3 | 0.70 |
| >=10 years | 3 | ( 0.2) | 3 | 0.28 | 2 | ( 0.1) | 2 | 0.22 |
| Paraesthesia | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.75 | 5 | ( 0.6) | 5 | 0.82 |
| >=10 years | 3 | ( 0.2) | 4 | 0.28 | 7 | ( 0.5) | 7 | 0.77 |
| Autonomic nervous system imbalance | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Somnolence | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.08 |
| Neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.08 |
| Post herpetic neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.20 | 1 | ( 0.1) | 1 | 0.15 |
| Amnesia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Dysgeusia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Cerebrovascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Memory impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.13 |
| Transient ischaemic attack | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.08 |
| Burning sensation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.20 |
| Carotid artery aneurysm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Cervicobrachial syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Facial paralysis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Peripheral paralysis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Thalamic infarction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Vascular headache | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Cerebral arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Vascular encephalopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Loss of consciousness | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |
| Sinus headache | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Speech disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Carotid artery stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Cerebral atrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Cluster headache | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Cognitive disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.13 |
| Cervical radiculopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Dizziness postural | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.27 |
| Neuroglycopenia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 3 | 0.23 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Presyncope | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 3 | ( 0.2) | 3 | 0.22 |
| Trigeminal neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Ageusia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Anosmia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Balance disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Basilar migraine | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Brain injury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Carotid arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Cerebral artery embolism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Cerebral haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Cerebral infarction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Cerebrovascular accident | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Dementia Alzheimer's type | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Disturbance in attention | | | | | | | | |
| <10 years | 2 | ( 0.3) | 10 | 2.56 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Encephalopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Essential tremor | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Facial nerve disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Haemorrhage intracranial | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Hemiparesis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Hypoglycaemic coma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Hypoglycaemic seizure | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hypoglycaemic unconsciousness | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hyporeflexia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Hypotonia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Intracranial pressure increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Ischaemic stroke | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Lethargy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): OTMTDURY DIABGR1; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD DIABGR1; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lumbar radiculopathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 3 | ( 0.2) | 4 | 0.29 |
| Mental impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Meralgia paraesthetica | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Morton's neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Myelopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Ophthalmic migraine | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Orthostatic tremor | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Parkinsonian gait | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Piriformis syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Radiculopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Restless legs syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Sleep deficit | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Thrombotic stroke | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Vertebral artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| White matter lesion | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 47 | ( 6.2) | 64 | 10.80 | 44 | ( 5.5) | 48 | 7.76 |
| >=10 years | 85 | ( 6.0) | 113 | 11.98 | 78 | ( 5.7) | 105 | 11.41 |
| Cough | | | | | | | | |
| <10 years | 9 | ( 1.2) | 10 | 1.78 | 9 | ( 1.1) | 9 | 1.21 |
| >=10 years | 17 | ( 1.2) | 19 | 1.93 | 19 | ( 1.4) | 21 | 2.51 |
| Oropharyngeal pain | | | | | | | | |
| <10 years | 11 | ( 1.5) | 12 | 1.77 | 4 | ( 0.5) | 5 | 0.75 |
| >=10 years | 13 | ( 0.9) | 14 | 1.52 | 15 | ( 1.1) | 16 | 1.77 |
| Rhinorrhoea | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.33 | 3 | ( 0.4) | 3 | 0.60 |
| >=10 years | 10 | ( 0.7) | 13 | 1.39 | 10 | ( 0.7) | 10 | 1.15 |
| Nasal congestion | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.40 | 3 | ( 0.4) | 3 | 0.37 |
| >=10 years | 7 | ( 0.5) | 7 | 0.60 | 2 | ( 0.1) | 2 | 0.22 |
| Dyspnoea | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.57 | 4 | ( 0.5) | 4 | 0.69 |
| >=10 years | 6 | ( 0.4) | 6 | 0.57 | 9 | ( 0.7) | 10 | 0.94 |
| Epistaxis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 1 | ( 0.1) | 2 | 0.25 |
| >=10 years | 5 | ( 0.4) | 9 | 1.14 | 1 | ( 0.1) | 2 | 0.25 |
| Sleep apnoea syndrome | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.48 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.34 | 0 | | | |
| Productive cough | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 3 | ( 0.2) | 3 | 0.42 |
| Chronic obstructive pulmonary disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 1 | ( 0.1) | 1 | 0.08 |
| Asthma | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.49 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Respiratory disorder | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 1.28 | 3 | ( 0.4) | 3 | 0.50 |
| >=10 years | 3 | ( 0.2) | 3 | 0.34 | 4 | ( 0.3) | 4 | 0.47 |
| Nasal septum deviation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.13 |
| Sinus congestion | | | | | | | | |
| <10 years | 4 | ( 0.5) | 5 | 0.90 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 2 | ( 0.1) | 2 | 0.22 |
| Sneezing | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.20 | 0 | | | |
| Rhinitis allergic | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.70 |
| >=10 years | 2 | ( 0.1) | 2 | 0.21 | 3 | ( 0.2) | 7 | 0.62 |
| Pulmonary fibrosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 3 | 0.26 | 0 | | | |
| Dyspnoea exertional | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.22 | 1 | ( 0.1) | 1 | 0.08 |
| Upper-airway cough syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.22 | 1 | ( 0.1) | 1 | 0.15 |
| Acute respiratory failure | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.08 |
| Nasal obstruction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |
| Respiratory failure | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |
| Bronchospasm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Emphysema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.35 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Pulmonary hypertension | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Sinus pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Bronchial hyperreactivity | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hiccups | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Pulmonary congestion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Acquired diaphragmatic eventration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Laryngeal cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Pulmonary embolism | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Pulmonary mass | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.57 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Acute pulmonary oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Allergic bronchitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Allergic cough | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Aphonia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Bronchiectasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Bronchitis chronic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Dry throat | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Dysphonia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.25 |
| Haemoptysis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Increased viscosity of upper respiratory secretion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Interstitial lung disease | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Lung disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Nasal dryness | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Nasal turbinate hypertrophy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Paranasal cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Paranasal sinus discomfort | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Pleural disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Pleural effusion | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |
| Pleurisy | | | | | | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 1 | ( 0.1) | 1 | 0.23 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Pleuritic pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Respiratory tract inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Throat irritation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.27 |
| Upper respiratory tract inflammation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Skin and subcutaneous tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 39 | ( 5.1) | 42 | 6.70 | 47 | ( 5.9) | 62 | 10.34 |
| >=10 years | 84 | ( 6.0) | 89 | 9.40 | 81 | ( 5.9) | 93 | 9.74 |
| Rash | | | | | | | | |
| <10 years | 6 | ( 0.8) | 6 | 1.08 | 3 | ( 0.4) | 3 | 0.37 |
| >=10 years | 8 | ( 0.6) | 8 | 0.87 | 8 | ( 0.6) | 9 | 0.76 |
| Pruritus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 6 | ( 0.4) | 6 | 0.58 | 10 | ( 0.7) | 10 | 1.06 |
| Alopecia | | | | | | | | |
| <10 years | 2 | ( 0.2) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.35 |
| >=10 years | 6 | ( 0.4) | 6 | 0.70 | 1 | ( 0.1) | 1 | 0.08 |
| Eczema | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.59 | 3 | ( 0.4) | 3 | 0.47 |
| >=10 years | 6 | ( 0.4) | 6 | 0.53 | 4 | ( 0.3) | 4 | 0.52 |
| Urticaria | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 8 | ( 1.0) | 8 | 1.20 |
| >=10 years | 5 | ( 0.4) | 5 | 0.57 | 4 | ( 0.3) | 4 | 0.45 |
| Dermatitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.49 | 3 | ( 0.4) | 4 | 0.69 |
| >=10 years | 5 | ( 0.4) | 5 | 0.58 | 4 | ( 0.3) | 4 | 0.42 |
| Dermatitis contact | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.41 | 4 | ( 0.5) | 4 | 0.72 |
| >=10 years | 5 | ( 0.4) | 5 | 0.50 | 10 | ( 0.7) | 10 | 1.16 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hyperhidrosis | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.61 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.44 | 5 | ( 0.4) | 5 | 0.46 |
| Skin ulcer | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.45 |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 3 | ( 0.2) | 3 | 0.32 |
| Cold sweat | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 7 | 1.62 |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 5 | ( 0.4) | 5 | 0.64 |
| Skin irritation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 3 | ( 0.2) | 4 | 0.43 | 1 | ( 0.1) | 1 | 0.07 |
| Miliaria | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 2 | ( 0.1) | 2 | 0.15 |
| Acne | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Hyperkeratosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 2 | ( 0.1) | 2 | 0.27 |
| Night sweats | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Skin lesion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.22 | 2 | ( 0.1) | 2 | 0.22 |
| Ingrowing nail | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.15 |
| Dry skin | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.41 | 4 | ( 0.5) | 4 | 0.71 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.07 |
| Rash papular | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Decubitus ulcer | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Ecchymosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.08 |
| Skin odour abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Intertrigo | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Umbilical haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Blister | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hidradenitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.07 |
| Ingrown hair | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Lichen sclerosus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Macule | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Rash erythematous | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Xeroderma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Dermatitis allergic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Angioedema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.22 |
| Lipodystrophy acquired | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Myxoid cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Skin fissures | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Urticaria contact | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Actinic keratosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Alopecia areata | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Asteatosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Chronic spontaneous urticaria | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Cold urticaria | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Dermal cyst | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 4 | ( 0.3) | 4 | 0.42 |
| Dermatitis atopic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.29 |
| Diabetic foot | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |
| Drug eruption | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Erythema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.19 |
| Granuloma annulare | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Haemorrhage subcutaneous | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Lentigo | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Leukoplakia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Lipohypertrophy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.20 |
| Livedo reticularis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Nail bed inflammation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Neurodermatitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Pruritus allergic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Psoriasis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Purpura | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Rash maculo-papular | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Seborrhoea | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Skin discolouration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Skin exfoliation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Skin reaction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Telangiectasia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Urticaria thermal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Metabolism and nutrition disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 48 | ( 6.3) | 64 | 9.94 | 61 | ( 7.7) | 76 | 12.33 |
| >=10 years | 84 | ( 5.9) | 99 | 9.47 | 73 | ( 5.3) | 93 | 9.25 |
| Hypoglycaemia | | | | | | | | |
| <10 years | 5 | ( 0.7) | 10 | 2.01 | 11 | ( 1.4) | 19 | 2.92 |
| >=10 years | 13 | ( 0.9) | 16 | 1.95 | 12 | ( 0.9) | 21 | 2.23 |
| Dyslipidaemia | | | | | | | | |
| <10 years | 8 | ( 1.1) | 9 | 1.51 | 10 | ( 1.3) | 10 | 1.83 |
| >=10 years | 13 | ( 0.9) | 13 | 1.28 | 7 | ( 0.5) | 7 | 0.77 |
| Vitamin D deficiency | | | | | | | | |
| <10 years | 7 | ( 0.9) | 7 | 0.90 | 9 | ( 1.1) | 9 | 1.41 |
| >=10 years | 10 | ( 0.7) | 10 | 0.82 | 5 | ( 0.4) | 5 | 0.44 |
| Hyperlipidaemia | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.75 | 8 | ( 1.0) | 8 | 1.19 |
| >=10 years | 9 | ( 0.6) | 9 | 0.84 | 5 | ( 0.4) | 5 | 0.46 |
| Hyperkalaemia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 3 | ( 0.4) | 3 | 0.49 |
| >=10 years | 6 | ( 0.4) | 7 | 0.65 | 7 | ( 0.5) | 7 | 0.72 |
| Hypertriglyceridaemia | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.54 | 6 | ( 0.7) | 6 | 0.95 |
| >=10 years | 6 | ( 0.4) | 6 | 0.58 | 2 | ( 0.1) | 2 | 0.25 |
| Hyperglycaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 5 | ( 0.6) | 5 | 0.72 |
| >=10 years | 5 | ( 0.4) | 6 | 0.63 | 9 | ( 0.7) | 9 | 1.02 |
| Vitamin B12 deficiency | | | | | | | | |
| <10 years | 7 | ( 0.9) | 7 | 0.89 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 4 | ( 0.3) | 4 | 0.27 | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hyperuricaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 3 | ( 0.2) | 3 | 0.28 | 1 | ( 0.1) | 1 | 0.07 |
| Decreased appetite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 5 | ( 0.4) | 5 | 0.41 |
| Fluid retention | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Hypercholesterolaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 3 | ( 0.4) | 3 | 0.59 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.15 |
| Hypokalaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 1 | ( 0.1) | 1 | 0.08 |
| Iron deficiency | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.39 | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.07 |
| Gout | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.1) | 3 | 0.21 | 5 | ( 0.4) | 6 | 0.43 |
| Increased appetite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.45 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 4 | ( 0.3) | 5 | 0.51 |
| Abnormal weight gain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Dehydration | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 3 | 0.37 |
| Hypoalbuminaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Hyponatraemia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.51 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.13 |
| Folate deficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Magnesium deficiency | | | | | | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Malnutrition | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Zinc deficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Obesity | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.47 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Appetite disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.15 |
| Diabetes mellitus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Diabetes mellitus inadequate control | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Electrolyte imbalance | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Food craving | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Hyperammonaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=10 years | 0 | | | | 0 | | | |
| Hypercalcaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Hypernatraemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Insulin resistance | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.22 |
| Lactic acidosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lipomatosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Metabolic acidosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Metabolic disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Vitamin B complex deficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Cardiac disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 35 | ( 4.6) | 48 | 7.20 | 27 | ( 3.4) | 38 | 6.24 |
| >=10 years | 60 | ( 4.2) | 85 | 7.57 | 57 | ( 4.2) | 77 | 6.81 |
| Atrial fibrillation | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.66 | 3 | ( 0.4) | 3 | 0.37 |
| >=10 years | 8 | ( 0.6) | 9 | 0.76 | 3 | ( 0.2) | 3 | 0.28 |
| Acute myocardial infarction | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 7 | ( 0.5) | 7 | 0.65 | 7 | ( 0.5) | 7 | 0.62 |
| Coronary artery disease | | | | | | | | |
| <10 years | 6 | ( 0.8) | 6 | 0.78 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 6 | ( 0.4) | 6 | 0.53 | 9 | ( 0.7) | 9 | 0.76 |
| Angina pectoris | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 6 | ( 0.4) | 6 | 0.55 | 4 | ( 0.3) | 4 | 0.34 |
| Myocardial infarction | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 5 | ( 0.4) | 5 | 0.51 | 3 | ( 0.2) | 3 | 0.22 |
| Ventricular extrasystoles | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.41 | 1 | ( 0.1) | 2 | 0.24 |
| >=10 years | 5 | ( 0.4) | 5 | 0.58 | 1 | ( 0.1) | 1 | 0.08 |
| Cardiac failure | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.40 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.40 | 3 | ( 0.2) | 4 | 0.47 |
| Cardiac failure congestive | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 3 | 0.67 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 4 | ( 0.3) | 4 | 0.33 | 0 | | | |
| Palpitations | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.67 | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 5 | ( 0.4) | 5 | 0.49 |
| Supraventricular extrasystoles | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.24 | 2 | ( 0.1) | 2 | 0.15 |
| Myocardial ischaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 3 | ( 0.2) | 3 | 0.29 |
| Arrhythmia | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.08 |
| Angina unstable | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.22 |
| Cardiac failure chronic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.08 |
| Coronary artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Left ventricular hypertrophy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.20 |
| Cardiac flutter | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Supraventricular tachycardia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Atrioventricular block first degree | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Cardio-respiratory arrest | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Aortic valve sclerosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Left atrial enlargement | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |
| Cardiomegaly | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Arteriosclerosis coronary artery | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Bundle branch block left | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.13 |
| Mitral valve incompetence | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.14 |
| Tachycardia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 4 | ( 0.5) | 4 | 0.79 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 3 | ( 0.2) | 3 | 0.22 |
| Acute coronary syndrome | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.39 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Atrial flutter | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Atrial thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Bundle branch block right | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 3 | ( 0.4) | 4 | 0.63 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 4 | ( 0.3) | 4 | 0.39 |
| Cardiac ventricular thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Diastolic dysfunction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Left atrial dilatation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Left ventricular dysfunction | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.22 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Pericardial effusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Tricuspid valve incompetence | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 3 | ( 0.2) | 3 | 0.22 |
| Aortic valve calcification | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Aortic valve incompetence | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Atrial enlargement | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Atrioventricular block complete | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Bradycardia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.37 |
| >=10 years | 0 | | | | 0 | | | |
| Cardiac arrest | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.14 |
| Cardiac dysfunction | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Cardiac failure acute | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Cardiac perfusion defect | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.25 |
| Cardiovascular disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Chronic coronary syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Coronary artery stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Mitral valve stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pericarditis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Sinus arrhythmia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Sinus bradycardia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 3 | ( 0.2) | 3 | 0.27 |
| Sinus tachycardia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Subendocardial ischaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Ventricular arrhythmia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Ventricular tachycardia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Investigations | | | | | | | | |
| All | | | | | | | | |
| <10 years | 38 | ( 5.0) | 40 | 7.10 | 33 | ( 4.1) | 37 | 5.39 |
| >=10 years | 56 | ( 4.0) | 69 | 6.94 | 46 | ( 3.4) | 51 | 5.96 |
| Weight increased | | | | | | | | |
| <10 years | 6 | ( 0.8) | 6 | 1.09 | 11 | ( 1.4) | 11 | 1.47 |
| >=10 years | 14 | ( 1.0) | 14 | 1.32 | 7 | ( 0.5) | 7 | 0.82 |
| Blood creatinine increased | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.48 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.62 | 0 | | | |
| Blood pressure increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 4 | ( 0.3) | 4 | 0.41 | 3 | ( 0.2) | 3 | 0.27 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| SARS-CoV-2 test positive | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.68 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 3 | ( 0.2) | 3 | 0.37 | 3 | ( 0.2) | 3 | 0.44 |
| Alanine aminotransferase increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 0 | | | |
| Blood cholesterol increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 3 | ( 0.2) | 3 | 0.29 | 0 | | | |
| Weight decreased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.21 | 1 | ( 0.1) | 1 | 0.15 |
| Blood alkaline phosphatase increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 0 | | | |
| Aspartate aminotransferase increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.08 |
| Liver function test increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.07 |
| Hepatic enzyme increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.21 | 2 | ( 0.1) | 2 | 0.22 |
| Prostatic specific antigen increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Arthroscopy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Occult blood | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Catheterisation cardiac | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Eosinophil count increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 2 | 0.29 |
| Liver function test abnormal | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 2 | 0.24 |
| Angiogram | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Electrocardiogram abnormal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.13 |
| Heart rate increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Low density lipoprotein increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.12 |
| Occult blood positive | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Blood immunoglobulin E increased | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.25 | 3 | ( 0.4) | 3 | 0.36 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Blood triglycerides increased | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.64 | 3 | ( 0.4) | 3 | 0.36 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Blood urine present | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 3 | 0.20 | 1 | ( 0.1) | 1 | 0.13 |
| Bone density decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Electrocardiogram ST segment abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| QRS axis abnormal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Body temperature increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| International normalised ratio abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| International normalised ratio decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| International normalised ratio increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Red blood cell count decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Amylase increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Antinuclear antibody positive | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Blood creatine increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood creatine phosphokinase increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood glucose decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Blood glucose fluctuation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood glucose increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.22 |
| Blood potassium increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Blood pressure decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Blood testosterone decreased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood uric acid increased | | | | | | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Breath sounds abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Carbohydrate antigen 19-9 increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Cardiac murmur | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.22 |
| Cardiac stress test abnormal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Ejection fraction decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Electrocardiogram P wave biphasic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Electrocardiogram repolarisation abnormality | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Electrocardiogram ST segment depression | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Electrocardiogram T wave inversion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Free fatty acids increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Glomerular filtration rate decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Glycosylated haemoglobin increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 2 | 0.24 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Grip strength decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Haematocrit increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Haemoglobin decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Haemoglobin increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Hepatitis B virus test positive | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Intraocular pressure increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Lipase increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Lipids abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Lipids increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Monocyte count decreased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Monofilament pressure perception test | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Mycobacterium tuberculosis complex test positive | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Platelet count decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Thyroid function test abnormal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Transaminases increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Transferrin saturation decreased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Vitamin D decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| White blood cell count decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Vascular disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 30 | ( 4.0) | 30 | 5.11 | 34 | ( 4.3) | 39 | 6.27 |
| >=10 years | 49 | ( 3.5) | 58 | 5.41 | 46 | ( 3.4) | 60 | 5.96 |
| Hypertension | | | | | | | | |
| <10 years | 15 | ( 2.0) | 15 | 2.76 | 19 | ( 2.4) | 20 | 3.34 |
| >=10 years | 22 | ( 1.6) | 22 | 2.17 | 19 | ( 1.4) | 23 | 2.36 |
| Hypotension | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.40 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 2 | ( 0.1) | 2 | 0.20 |
| Peripheral arterial occlusive disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 4 | 0.33 | 1 | ( 0.1) | 1 | 0.08 |
| Arteriosclerosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.34 |
| >=10 years | 3 | ( 0.2) | 3 | 0.28 | 5 | ( 0.4) | 5 | 0.47 |
| Superficial vein thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.21 | 0 | | | |
| Orthostatic hypotension | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 0 | | | |
| Haematoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 2 | ( 0.1) | 2 | 0.20 |
| Peripheral artery stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 5 | 0.51 | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Peripheral venous disease | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.47 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Aortic arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.25 |
| Deep vein thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Diabetic vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.25 |
| Blood pressure inadequately controlled | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.15 |
| Aortic stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Brachiocephalic arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Hypertensive urgency | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 3 | 0.27 |
| Peripheral artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Peripheral coldness | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Peripheral vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Varicose vein | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 3 | ( 0.2) | 3 | 0.29 |
| Aneurysm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Aortic aneurysm | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Aortic dilatation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Arterial insufficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood pressure fluctuation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Flushing | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Hot flush | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Hypertensive crisis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.23 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 3 | 0.38 |
| Iliac artery stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Intermittent claudication | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Macroangiopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Neovascularisation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Peripheral artery aneurysm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Peripheral ischaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Phlebitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Thrombophlebitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Thrombosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Varicose ulceration | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Venous stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Renal and urinary disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 19 | ( 2.5) | 24 | 4.13 | 19 | ( 2.4) | 26 | 3.79 |
| >=10 years | 35 | ( 2.5) | 41 | 3.95 | 35 | ( 2.6) | 44 | 4.21 |
| Renal impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 3 | ( 0.2) | 3 | 0.22 |
| Nephrolithiasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 3 | 0.46 |
| >=10 years | 4 | ( 0.3) | 4 | 0.28 | 2 | ( 0.1) | 3 | 0.32 |
| Pollakiuria | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.45 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 2 | ( 0.1) | 2 | 0.15 |
| Acute kidney injury | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 3 | ( 0.2) | 3 | 0.22 |
| Renal cyst | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.68 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 3 | ( 0.2) | 3 | 0.32 | 4 | ( 0.3) | 4 | 0.42 |
| Dysuria | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 4 | 0.33 | 3 | ( 0.2) | 3 | 0.28 |
| Diabetic nephropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.1) | 2 | 0.20 | 3 | ( 0.2) | 3 | 0.39 |
| Urine odour abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 2 | ( 0.1) | 2 | 0.20 | 1 | ( 0.1) | 1 | 0.12 |
| Chronic kidney disease | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.25 | 5 | ( 0.4) | 5 | 0.49 |
| Renal pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.21 | 0 | | | |
| Nephrotic syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Polyuria | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.07 |
| Chromaturia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Ureterolithiasis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.08 |
| Haematuria | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 2 | 0.25 | 4 | ( 0.3) | 4 | 0.34 |
| Hypertonic bladder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Urinary tract disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Microalbuminuria | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Nocturia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.15 |
| Pyelocaliectasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Renal colic | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.34 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.12 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Bladder mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Bladder prolapse | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Calculus urinary | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Cystitis haemorrhagic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Hydrocalyx | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.27 |
| Hydronephrosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Hypertensive nephropathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Micturition urgency | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Nephropathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Proteinuria | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Renal failure | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Renal mass | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Strangury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Stress urinary incontinence | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Urethral stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Urinary incontinence | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 3 | ( 0.4) | 3 | 0.36 |
| >=10 years | 0 | | | | 0 | | | |
| Urinary retention | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.15 |
| Urinary tract inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Urinary tract obstruction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Psychiatric disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 17 | ( 2.2) | 18 | 3.15 | 13 | ( 1.6) | 14 | 2.65 |
| >=10 years | 24 | ( 1.7) | 27 | 2.47 | 30 | ( 2.2) | 32 | 3.29 |
| Insomnia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=10 years | 9 | ( 0.6) | 9 | 0.92 | 6 | ( 0.4) | 7 | 0.67 |
| Depression | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.39 | 8 | ( 1.0) | 8 | 1.46 |
| >=10 years | 5 | ( 0.4) | 5 | 0.46 | 4 | ( 0.3) | 4 | 0.44 |
| Anxiety | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.49 | 2 | ( 0.2) | 2 | 0.50 |
| >=10 years | 3 | ( 0.2) | 3 | 0.28 | 8 | ( 0.6) | 8 | 0.73 |
| Sleep disorder | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.21 | 4 | ( 0.3) | 4 | 0.49 |
| Adjustment disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Mental status changes | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Adjustment disorder with mixed anxiety and | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| depressed mood | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Disorientation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Irritability | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Stress | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Nightmare | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Adjustment disorder with depressed mood | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Affect lability | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Agitation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Anxiety disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Attention deficit hyperactivity disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Bruxism | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Depressed mood | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.41 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Drug abuse | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Drug dependence | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Emotional distress | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Fear | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Listless | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Major depression | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Mixed anxiety and depressive disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Mood swings | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Persistent depressive disorder | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Phobia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Post-traumatic stress disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood and lymphatic system disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 12 | ( 1.6) | 14 | 2.58 | 13 | ( 1.6) | 13 | 2.01 |
| >=10 years | 24 | ( 1.7) | 24 | 2.27 | 20 | ( 1.5) | 20 | 2.00 |
| Anaemia | | | | | | | | |
| <10 years | 8 | ( 1.0) | 10 | 1.97 | 4 | ( 0.5) | 4 | 0.50 |
| >=10 years | 12 | ( 0.8) | 12 | 1.07 | 10 | ( 0.7) | 10 | 0.99 |
| Lymphadenopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.28 | 1 | ( 0.1) | 1 | 0.15 |
| Iron deficiency anaemia | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 3 | ( 0.2) | 3 | 0.29 |
| Blood loss anaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.15 |
| Eosinophilia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 2 | ( 0.1) | 2 | 0.20 |
| Lymphadenopathy mediastinal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Lymphadenitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Splenomegaly | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Polycythaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Thrombocytopenia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.15 |
| Hypochromic anaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Leukocytosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.24 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Leukopenia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Normocytic anaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Pancytopenia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Thrombocytosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Reproductive system and breast disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 10 | ( 1.3) | 10 | 1.73 | 12 | ( 1.5) | 16 | 2.78 |
| >=10 years | 23 | ( 1.6) | 23 | 2.18 | 15 | ( 1.1) | 17 | 1.54 |
| Benign prostatic hyperplasia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 6 | ( 0.4) | 6 | 0.60 | 2 | ( 0.1) | 2 | 0.20 |
| Erectile dysfunction | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.26 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 3 | ( 0.2) | 3 | 0.26 | 0 | | | |
| Uterine polyp | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Prostatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Prostatic calcification | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Dysmenorrhoea | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |
| Premenstrual syndrome | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Prostatomegaly | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Atrophic vulvovaginitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Breast mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Menopausal symptoms | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Ovarian cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Pruritus genital | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.20 |
| Uterine prolapse | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Vulvovaginal pruritus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.08 |
| Breast pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Cervical polyp | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Colpocele | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Ectropion of cervix | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Ejaculation failure | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Fibrocystic breast disease | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Galactorrhoea | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Genital prolapse | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Intermenstrual bleeding | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.45 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Menopausal disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Menstruation delayed | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Menstruation irregular | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Ovarian disorder | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Pelvic discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Penile pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Penile rash | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.15 |
| Testicular cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Uterine enlargement | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Vaginal discharge | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.34 |
| >=10 years | 0 | | | | 0 | | | |
| Vaginal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.14 |
| Vulvovaginal dryness | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | | | | | |
| All | | | | | | | | |
| <10 years | 13 | ( 1.7) | 16 | 2.79 | 6 | ( 0.8) | 11 | 1.44 |
| >=10 years | 22 | ( 1.6) | 27 | 2.47 | 23 | ( 1.7) | 32 | 3.10 |
| Adenocarcinoma pancreas | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Colon adenoma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Pancreatic neoplasm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Metastases to liver | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 1 | ( 0.1) | 1 | 0.07 |
| Chronic myeloid leukaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Gastric cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Eye naevus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.52 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Osteoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Benign neoplasm of thyroid gland | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Haemangioma of liver | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Melanocytic naevus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Bladder cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Colorectal cancer | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Invasive ductal breast carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Invasive lobular breast carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Lipoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Pancreatic carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Renal neoplasm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Squamous cell carcinoma of skin | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Basal cell carcinoma | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 1 | ( 0.1) | 1 | 0.07 |
| Glioblastoma multiforme | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Prostate cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Seborrhoeic keratosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.27 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Acrochordon | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Adenocarcinoma of colon | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Adrenal adenoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Benign renal neoplasm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.22 |
| Bladder papilloma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Bowen's disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Breast cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Breast cancer metastatic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Colon cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Colon cancer stage II | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Dysplastic naevus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Endometrial adenocarcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Gastrointestinal tract adenoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Hepatocellular carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Invasive breast carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Lung adenocarcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.1) | 2 | 0.25 |
| Lung cancer metastatic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Lymphangioma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Malignant melanoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Malignant melanoma in situ | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Malignant peritoneal neoplasm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Metastases to bone marrow | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Metastases to lymph nodes | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Myxoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Neoplasm skin | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Oral fibroma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Ovarian cancer metastatic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Pancreatic carcinoma metastatic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Prostatic adenoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Renal cell carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Renal hamartoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Salivary gland neoplasm | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Skin papilloma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Small cell lung cancer | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Small intestine neuroendocrine tumour | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Uterine cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Uterine leiomyoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 4 | ( 0.3) | 4 | 0.50 |
| Ear and labyrinth disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 11 | ( 1.4) | 11 | 1.66 | 5 | ( 0.6) | 5 | 0.82 |
| >=10 years | 17 | ( 1.2) | 20 | 1.80 | 19 | ( 1.4) | 20 | 2.02 |
| Vertigo | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.40 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 7 | ( 0.5) | 8 | 0.77 | 8 | ( 0.6) | 9 | 0.90 |
| Ear pain | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.68 | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.21 | 2 | ( 0.1) | 2 | 0.27 |
| Deafness bilateral | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Vertigo positional | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Cerumen impaction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.13 |
| Deafness neurosensory | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| External ear pain | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Hypoacusis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.19 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 3 | ( 0.2) | 3 | 0.22 |
| Ear inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Tinnitus | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 2 | ( 0.1) | 2 | 0.20 |
| Deafness unilateral | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Ear discomfort | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Eustachian tube dysfunction | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Meniere's disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Middle ear inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Motion sickness | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Presbyacusis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Hepatobiliary disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 8 | ( 1.1) | 12 | 1.87 | 14 | ( 1.7) | 17 | 2.69 |
| >=10 years | 16 | ( 1.1) | 19 | 2.05 | 11 | ( 0.8) | 12 | 1.37 |
| Hepatic steatosis | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.62 | 7 | ( 0.9) | 7 | 1.06 |
| >=10 years | 7 | ( 0.5) | 7 | 0.72 | 3 | ( 0.2) | 3 | 0.34 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gallbladder polyp | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 2 | ( 0.1) | 2 | 0.29 |
| Cholelithiasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 0 | | | |
| Alcoholic liver disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Cholecystitis chronic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Hepatomegaly | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Hyperplastic cholecystopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Hepatic calcification | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hypertransaminasaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.27 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hepatic mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Gallbladder cholesterolosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Bile duct stone | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.14 |
| Biliary colic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Biliary dyskinesia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Cholecystitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Gallbladder disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hepatic cirrhosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Hepatic cyst | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Hepatic function abnormal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 0 | | | | 0 | | | |
| Liver disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| Non-alcoholic steatohepatitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Nonalcoholic fatty liver disease | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Steatohepatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Immune system disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 6 | ( 0.8) | 7 | 1.12 | 6 | ( 0.8) | 7 | 1.21 |
| >=10 years | 8 | ( 0.6) | 8 | 0.85 | 10 | ( 0.7) | 10 | 1.11 |
| Seasonal allergy | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.58 | 3 | ( 0.4) | 3 | 0.49 |
| >=10 years | 4 | ( 0.3) | 4 | 0.33 | 6 | ( 0.4) | 6 | 0.67 |
| Hypersensitivity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.27 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.27 | 0 | | | |
| Anaphylactic reaction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 1 | ( 0.1) | 1 | 0.12 |
| Drug hypersensitivity | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Allergy to arthropod bite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.24 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Allergy to arthropod sting | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Food allergy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Immunisation reaction | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Endocrine disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 0 | | | | 10 | ( 1.2) | 10 | 1.56 |
| >=10 years | 6 | ( 0.4) | 6 | 0.52 | 9 | ( 0.7) | 9 | 0.85 |
| Hypothyroidism | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.37 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 3 | ( 0.2) | 3 | 0.26 |
| Thyroid mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.1) | 2 | 0.14 | 2 | ( 0.1) | 2 | 0.19 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hypogonadism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Autoimmune thyroiditis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Adrenal mass | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Adrenocortical insufficiency acute | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Goitre | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Hyperplasia adrenal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Hyperprolactinaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Hyperthyroidism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Inappropriate antidiuretic hormone secretion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| Secondary hypogonadism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Surgical and medical procedures | | | | | | | | |
| All | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.2) | 2 | 0.35 |
| >=10 years | 5 | ( 0.4) | 5 | 0.61 | 4 | ( 0.3) | 4 | 0.34 |
| Shoulder operation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Tooth extraction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Cardiac ablation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Skin neoplasm excision | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.07 |
| Cardiac pacemaker replacement | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Knee operation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Large intestinal polypectomy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Removal of foreign body | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Spinal operation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Toe amputation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Congenital, familial and genetic disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 3 | ( 0.4) | 3 | 0.46 |
| >=10 years | 5 | ( 0.4) | 5 | 0.51 | 2 | ( 0.1) | 2 | 0.15 |
| Type V hyperlipidaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 2 | ( 0.1) | 2 | 0.19 | 0 | | | |
| Cystic fibrosis lung | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Corneal dystrophy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.12 | 0 | | | |
| Hydrocele | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.07 | 0 | | | |
| Atrial septal defect | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.07 |
| Congenital syphilitic osteochondritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Hypertrophic cardiomyopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Myotonic dystrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.12 |
| >=10 years | 0 | | | | 0 | | | |
| Social circumstances | | | | | | | | |
| All | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |
| Menopause | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

## 7.7.52 Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on- treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <10 years | 689 | | | | 714 | | | |
| >=10 years | 1191 | | | | 1164 | | | |
| PYE (years) | | | | | | | | |
| <10 years | 589.76 | | | | 616.53 | | | |
| >=10 years | 949.16 | | | | 919.93 | | | |
| Events | | | | | | | | |
| <10 years | 399 | (58.0) | 1222 | 216.31 | 416 | (58.2) | 1250 | 214.60 |
| >=10 years | 740 | (62.1) | 2256 | 251.73 | 657 | (56.5) | 2009 | 228.61 |
| Infections and infestations | | | | | | | | |
| All | | | | | | | | |
| <10 years | 193 | (28.0) | 288 | 51.41 | 195 | (27.1) | 308 | 50.94 |
| >=10 years | 351 | (29.4) | 485 | 54.85 | 328 | (28.3) | 449 | 51.01 |
| COVID-19 | | | | | | | | |
| <10 years | 62 | ( 9.1) | 63 | 11.05 | 59 | ( 8.2) | 61 | 9.90 |
| >=10 years | 90 | ( 7.5) | 92 | 10.20 | 101 | ( 8.8) | 104 | 10.91 |
| Nasopharyngitis | | | | | | | | |
| <10 years | 34 | ( 4.8) | 43 | 8.08 | 27 | ( 3.8) | 30 | 4.80 |
| >=10 years | 49 | ( 4.1) | 56 | 6.29 | 52 | ( 4.5) | 62 | 7.52 |
| Upper respiratory tract infection | | | | | | | | |
| <10 years | 23 | ( 3.4) | 30 | 4.83 | 18 | ( 2.5) | 19 | 3.17 |
| >=10 years | 39 | ( 3.3) | 45 | 5.10 | 27 | ( 2.3) | 29 | 3.28 |
| Urinary tract infection | | | | | | | | |
| <10 years | 11 | ( 1.6) | 11 | 2.05 | 16 | ( 2.2) | 17 | 2.89 |
| >=10 years | 26 | ( 2.2) | 29 | 3.32 | 28 | ( 2.4) | 31 | 3.21 |
| Influenza | | | | | | | | |
| <10 years | 12 | ( 1.7) | 13 | 2.93 | 10 | ( 1.4) | 11 | 2.17 |
| >=10 years | 16 | ( 1.4) | 18 | 2.42 | 18 | ( 1.5) | 20 | 2.79 |
| Gastroenteritis | | | | | | | | |
| <10 years | 11 | ( 1.6) | 11 | 2.16 | 8 | ( 1.1) | 8 | 1.45 |
| >=10 years | 15 | ( 1.3) | 15 | 2.06 | 8 | ( 0.7) | 9 | 1.26 |
| Bronchitis | | | | | | | | |
| <10 years | 11 | ( 1.6) | 11 | 2.12 | 9 | ( 1.3) | 9 | 1.56 |
| >=10 years | 15 | ( 1.3) | 16 | 1.82 | 8 | ( 0.7) | 8 | 0.93 |
| COVID-19 pneumonia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 5 | ( 0.7) | 5 | 0.91 |
| >=10 years | 12 | ( 1.0) | 12 | 1.37 | 5 | ( 0.4) | 5 | 0.48 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Sinusitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.44 | 4 | ( 0.6) | 7 | 1.07 |
| >=10 years | 12 | ( 1.0) | 13 | 1.45 | 13 | ( 1.1) | 13 | 1.48 |
| Pneumonia | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.54 | 3 | ( 0.4) | 3 | 0.64 |
| >=10 years | 11 | ( 0.9) | 11 | 1.29 | 3 | ( 0.3) | 3 | 0.31 |
| Cystitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 9 | ( 1.3) | 10 | 1.84 |
| >=10 years | 10 | ( 0.8) | 11 | 1.22 | 7 | ( 0.6) | 8 | 0.87 |
| Pharyngitis | | | | | | | | |
| <10 years | 7 | ( 1.0) | 7 | 1.28 | 8 | ( 1.1) | 10 | 1.50 |
| >=10 years | 9 | ( 0.7) | 11 | 1.04 | 9 | ( 0.8) | 10 | 1.30 |
| Respiratory tract infection viral | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.67 | 3 | ( 0.4) | 3 | 0.64 |
| >=10 years | 7 | ( 0.6) | 7 | 0.90 | 5 | ( 0.4) | 6 | 0.83 |
| Herpes zoster | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.56 | 6 | ( 0.8) | 7 | 0.96 |
| >=10 years | 7 | ( 0.6) | 7 | 0.64 | 9 | ( 0.8) | 9 | 1.01 |
| Conjunctivitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 3 | ( 0.4) | 3 | 0.52 |
| >=10 years | 6 | ( 0.5) | 6 | 0.62 | 4 | ( 0.3) | 4 | 0.47 |
| Respiratory tract infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 3 | ( 0.4) | 3 | 0.53 |
| >=10 years | 6 | ( 0.5) | 6 | 0.68 | 3 | ( 0.3) | 3 | 0.33 |
| Otitis media | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.37 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 5 | ( 0.4) | 5 | 0.67 | 3 | ( 0.3) | 3 | 0.37 |
| Fungal infection | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.55 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 5 | 0.60 | 2 | ( 0.2) | 2 | 0.24 |
| Vaginal infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 4 | ( 0.3) | 4 | 0.45 | 1 | ( 0.1) | 1 | 0.14 |
| Tooth infection | | | | | | | | |
| <10 years | 4 | ( 0.6) | 6 | 1.00 | 3 | ( 0.5) | 3 | 0.67 |
| >=10 years | 4 | ( 0.3) | 4 | 0.45 | 5 | ( 0.4) | 5 | 0.67 |
| Viral infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 6 | ( 0.8) | 9 | 1.34 |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 3 | ( 0.3) | 3 | 0.25 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Periodontitis | | | | | | | | |
| <10 years | 0 | | | | 4 | ( 0.6) | 4 | 0.66 |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 2 | ( 0.2) | 2 | 0.29 |
| Tooth abscess | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.61 | 3 | ( 0.4) | 3 | 0.41 |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 4 | ( 0.3) | 5 | 0.62 |
| Rhinitis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.45 | 3 | ( 0.4) | 3 | 0.42 |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 4 | ( 0.3) | 6 | 0.81 |
| Cellulitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 5 | ( 0.7) | 6 | 1.42 |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 3 | ( 0.3) | 3 | 0.26 |
| Ear infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 3 | ( 0.3) | 3 | 0.38 |
| Acute sinusitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 2 | ( 0.2) | 2 | 0.23 |
| Gastroenteritis viral | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 2 | ( 0.2) | 2 | 0.23 |
| Localised infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 1 | ( 0.1) | 1 | 0.14 |
| Coronavirus infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 4 | 0.56 |
| >=10 years | 3 | ( 0.2) | 3 | 0.25 | 1 | ( 0.1) | 2 | 0.30 |
| Lower respiratory tract infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.25 | 2 | ( 0.2) | 4 | 0.36 |
| Helicobacter infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.23 |
| Oral herpes | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 2 | ( 0.2) | 3 | 0.44 | 0 | | | |
| Onychomycosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.17 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Otitis externa | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 2 | ( 0.2) | 2 | 0.17 |
| Wound infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 1 | ( 0.1) | 1 | 0.14 |
| Abscess | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Osteomyelitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Vulvovaginal mycotic infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Gingivitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 3 | 0.25 | 4 | ( 0.3) | 4 | 0.52 |
| Hordeolum | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 2 | ( 0.2) | 2 | 0.29 |
| Enteritis infectious | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Kidney infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Pustule | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Subcutaneous abscess | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 2 | 0.28 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Tonsillitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| Varicella zoster virus infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vulvitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Escherichia bacteraemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Furuncle | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.30 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Genital candidiasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Injection site abscess | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Postoperative wound infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.08 |
| Skin infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Suspected COVID-19 | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Tinea pedis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.14 |
| Bacteraemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Cholecystitis infective | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Diabetic foot infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Infected dermal cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Paronychia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 3 | 0.44 |
| Pharyngotonsillitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 2 | 0.18 |
| Pneumonia viral | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Pulmonary tuberculoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Respiratory syncytial virus infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Sepsis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Viral tracheitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Clostridium difficile colitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Clostridium difficile infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Erysipelas | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 1 | ( 0.1) | 2 | 0.49 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Fungal skin infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.15 |
| Gangrene | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Genital infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.39 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Nail infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.09 |
| Peritonsillar abscess | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.14 |
| Pyelonephritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Tinea cruris | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Viral pharyngitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Asymptomatic COVID-19 | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.24 |
| Balanitis candida | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Candida infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.15 |
| Chlamydial infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Chronic tonsillitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Dermatophytosis of nail | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Helicobacter gastritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Herpes virus infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Infected bite | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Laryngitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 2 | ( 0.3) | 2 | 0.50 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.18 |
| Mastitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Oropharyngeal candidiasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Otitis media chronic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Pericoronitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Purulence | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Abdominal abscess | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Abscess limb | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Acarodermatitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 3 | ( 0.3) | 3 | 0.26 |
| Anal abscess | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Appendicitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Bacterial infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Bartholinitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Body tinea | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Breast abscess | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Breast cellulitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Campylobacter gastroenteritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Chronic hepatitis C | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Chronic sinusitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Diverticulitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 5 | ( 0.4) | 5 | 0.44 |
| Ear infection fungal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Empyema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Endophthalmitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Epididymitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Escherichia urinary tract infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Eye infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.30 |
| Eye infection bacterial | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Folliculitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Fungal balanitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Gastroenteritis norovirus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Gastrointestinal infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.46 | 3 | ( 0.4) | 4 | 0.54 |
| >=10 years | 0 | | | | 0 | | | |
| Genital infection fungal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Giardiasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Herpes dermatitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Herpes simplex | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Herpes zoster infection neurological | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Infective iritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Labyrinthitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Laryngopharyngitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 2 | 0.27 |
| >=10 years | 0 | | | | 0 | | | |
| Lyme disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Oophoritis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Oral candidiasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Otitis media acute | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Paraspinal abscess | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Parotitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Peri-implantitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Post procedural infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Post-acute COVID-19 syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.28 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pulpitis dental | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 3 | ( 0.3) | 3 | 0.44 |
| Rotavirus infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Salpingitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Sinusitis bacterial | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Skin bacterial infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Skin candida | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Soft tissue infection | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.29 |
| Sweat gland infection | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Tinea infection | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Tinea versicolour | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Tracheitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Urethritis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Urosepsis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Varicella | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Viral rhinitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Viral upper respiratory tract infection | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.18 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vulvovaginal candidiasis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.67 | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.18 |
| Gastrointestinal disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 82 | (11.9) | 126 | 21.67 | 82 | (11.5) | 113 | 19.86 |
| >=10 years | 169 | (14.2) | 254 | 28.15 | 139 | (12.0) | 189 | 21.78 |
| Diarrhoea | | | | | | | | |
| <10 years | 18 | ( 2.6) | 21 | 3.44 | 19 | ( 2.7) | 19 | 3.54 |
| >=10 years | 66 | ( 5.5) | 81 | 9.10 | 32 | ( 2.8) | 33 | 3.88 |
| Nausea | | | | | | | | |
| <10 years | 13 | ( 1.9) | 14 | 2.40 | 11 | ( 1.6) | 11 | 1.97 |
| >=10 years | 24 | ( 2.0) | 24 | 2.68 | 16 | ( 1.4) | 18 | 2.03 |
| Vomiting | | | | | | | | |
| <10 years | 9 | ( 1.3) | 12 | 2.63 | 6 | ( 0.8) | 7 | 1.21 |
| >=10 years | 15 | ( 1.3) | 20 | 2.40 | 10 | ( 0.9) | 12 | 1.29 |
| Abdominal pain | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.90 | 8 | ( 1.1) | 8 | 1.21 |
| >=10 years | 11 | ( 0.9) | 11 | 1.16 | 10 | ( 0.9) | 11 | 1.43 |
| Constipation | | | | | | | | |
| <10 years | 6 | ( 0.9) | 6 | 1.12 | 5 | ( 0.7) | 5 | 1.24 |
| >=10 years | 10 | ( 0.8) | 13 | 1.58 | 11 | ( 1.0) | 11 | 1.19 |
| Gastrooesophageal reflux disease | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.54 | 4 | ( 0.5) | 4 | 0.55 |
| >=10 years | 10 | ( 0.8) | 10 | 1.01 | 10 | ( 0.9) | 10 | 1.22 |
| Abdominal pain upper | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.67 | 7 | ( 1.0) | 8 | 1.23 |
| >=10 years | 9 | ( 0.8) | 11 | 1.22 | 8 | ( 0.7) | 8 | 0.92 |
| Dental caries | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.57 | 4 | ( 0.6) | 4 | 0.54 |
| >=10 years | 7 | ( 0.6) | 9 | 0.74 | 6 | ( 0.5) | 6 | 0.88 |
| Chronic gastritis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 6 | ( 0.5) | 6 | 0.69 | 2 | ( 0.2) | 2 | 0.18 |
| Toothache | | | | | | | | |
| <10 years | 7 | ( 1.0) | 7 | 1.05 | 4 | ( 0.6) | 5 | 1.13 |
| >=10 years | 6 | ( 0.5) | 6 | 0.62 | 6 | ( 0.5) | 8 | 1.10 |
| Dyspepsia | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.61 | 3 | ( 0.4) | 3 | 0.51 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 5 | ( 0.4) | 5 | 0.55 |
| Gastritis | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.64 | 3 | ( 0.4) | 3 | 0.65 |
| >=10 years | 4 | ( 0.3) | 4 | 0.45 | 6 | ( 0.5) | 6 | 0.63 |
| Large intestine polyp | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 4 | ( 0.3) | 5 | 0.49 |
| Food poisoning | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 4 | ( 0.3) | 5 | 0.67 |
| Flatulence | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.38 | 2 | ( 0.2) | 2 | 0.29 |
| Abdominal distension | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.59 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 3 | ( 0.3) | 3 | 0.39 |
| Abdominal pain lower | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.08 |
| Hiatus hernia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.09 |
| Hypoaesthesia oral | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 4 | 0.58 | 0 | | | |
| Haemorrhoids | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.80 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.29 |
| Abdominal discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 2 | 0.50 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 4 | ( 0.3) | 4 | 0.41 |
| Aphthous ulcer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Diverticulum intestinal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Dry mouth | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.09 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gingival bleeding | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Intra-abdominal haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.09 |
| Tongue rough | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Noninfective gingivitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Oral pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Pancreatic duct dilatation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Pancreatic failure | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Pancreatitis chronic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.09 |
| Proctalgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Abdominal wall disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Diabetic gastropathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Eosinophilic oesophagitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Eructation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Gastrointestinal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Haemorrhoidal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Impaired gastric emptying | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Inguinal hernia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 2 | 0.18 |
| Intestinal dilatation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Colitis ischaemic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Enterocolitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.45 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Frequent bowel movements | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Haematochezia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Hyperaesthesia teeth | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Pancreatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Acid peptic disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.18 |
| Anal fissure | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 0 | | | | 0 | | | |
| Anal pruritus | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Colitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 0 | | | | 0 | | | |
| Colitis microscopic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Crohn's disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Diverticulum | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.23 |
| Duodenitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Enteritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Epigastric discomfort | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Faeces pale | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Gastric dilatation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gastric disorder | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Gastric dysplasia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Gastric mucosal hypertrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 0 | | | | 0 | | | |
| Gastric polyps | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Gastric ulcer | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Gastrointestinal angiodysplasia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gastrointestinal disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Gastrointestinal inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Gastrointestinal sounds abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Gingival disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hyperchlorhydria | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Ileus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Irritable bowel syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Lip swelling | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Loose tooth | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Melaena | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Mesenteric panniculitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Odynophagia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Oesophageal pain | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Oesophagitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Oral discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pancreatic pseudocyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Pancreatitis acute | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Peptic ulcer | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Periodontal disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.29 |
| Periodontal inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.18 |
| Rectal polyp | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 0 | | | | 0 | | | |
| Rectal prolapse | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Small intestinal obstruction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Stomatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Tooth disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Tooth impacted | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.25 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Ulcerative gastritis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Umbilical hernia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.18 |
| Upper gastrointestinal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Vomiting projectile | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 77 | (11.2) | 109 | 18.57 | 95 | (13.3) | 127 | 22.59 |
| >=10 years | 169 | (14.2) | 260 | 28.56 | 150 | (12.9) | 211 | 23.62 |
| Back pain | | | | | | | | |
| <10 years | 19 | ( 2.7) | 19 | 3.60 | 16 | ( 2.2) | 17 | 3.26 |
| >=10 years | 43 | ( 3.6) | 47 | 4.94 | 45 | ( 3.9) | 47 | 5.44 |
| Arthralgia | | | | | | | | |
| <10 years | 16 | ( 2.3) | 19 | 3.42 | 17 | ( 2.4) | 19 | 3.69 |
| >=10 years | 29 | ( 2.4) | 34 | 3.70 | 31 | ( 2.7) | 35 | 3.98 |
| Pain in extremity | | | | | | | | |
| <10 years | 10 | ( 1.5) | 11 | 1.68 | 8 | ( 1.1) | 9 | 1.92 |
| >=10 years | 21 | ( 1.7) | 22 | 2.19 | 23 | ( 2.0) | 28 | 3.19 |
| Muscle spasms | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.90 | 3 | ( 0.4) | 3 | 0.42 |
| >=10 years | 18 | ( 1.5) | 20 | 2.43 | 6 | ( 0.5) | 6 | 0.70 |
| Osteoarthritis | | | | | | | | |
| <10 years | 4 | ( 0.6) | 5 | 0.74 | 9 | ( 1.2) | 10 | 1.57 |
| >=10 years | 17 | ( 1.4) | 18 | 1.93 | 15 | ( 1.3) | 17 | 1.97 |
| Neck pain | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.44 | 4 | ( 0.6) | 4 | 0.66 |
| >=10 years | 12 | ( 1.0) | 12 | 1.44 | 4 | ( 0.3) | 4 | 0.41 |
| Myalgia | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.80 | 4 | ( 0.6) | 4 | 0.77 |
| >=10 years | 10 | ( 0.8) | 10 | 1.21 | 5 | ( 0.4) | 5 | 0.60 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Trigger finger | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 5 | 0.82 |
| >=10 years | 6 | ( 0.5) | 6 | 0.81 | 2 | ( 0.2) | 2 | 0.17 |
| Tendonitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 6 | ( 0.5) | 8 | 0.91 | 3 | ( 0.3) | 3 | 0.33 |
| Periarthritis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 4 | ( 0.5) | 4 | 0.67 |
| >=10 years | 6 | ( 0.5) | 6 | 0.63 | 2 | ( 0.2) | 2 | 0.17 |
| Rotator cuff syndrome | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.40 |
| >=10 years | 5 | ( 0.4) | 5 | 0.54 | 1 | ( 0.1) | 1 | 0.08 |
| Intervertebral disc protrusion | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.51 | 3 | ( 0.4) | 4 | 0.66 |
| >=10 years | 5 | ( 0.4) | 9 | 0.80 | 3 | ( 0.3) | 3 | 0.32 |
| Spinal stenosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 4 | ( 0.3) | 6 | 0.76 | 0 | | | |
| Spinal osteoarthritis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 3 | ( 0.3) | 4 | 0.34 |
| Muscular weakness | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 2 | ( 0.2) | 2 | 0.23 |
| Musculoskeletal chest pain | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.2) | 3 | 0.25 | 1 | ( 0.1) | 1 | 0.08 |
| Osteoporosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 0 | | | |
| Musculoskeletal stiffness | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 0 | | | |
| Arthritis | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.68 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 4 | ( 0.3) | 4 | 0.52 |
| Tendon disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 1 | ( 0.1) | 1 | 0.15 |
| Foot deformity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.28 | 1 | ( 0.1) | 1 | 0.25 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 2 | ( 0.2) | 3 | 0.31 | 2 | ( 0.2) | 2 | 0.23 |
| Osteochondrosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.30 |
| Bursitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.36 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 2 | ( 0.2) | 2 | 0.18 |
| Chondropathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Groin pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.09 |
| Plantar fasciitis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.37 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 3 | 0.25 | 2 | ( 0.2) | 2 | 0.17 |
| Axillary mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.09 |
| Flank pain | | | | | | | | |
| <10 years | 0 | | | | 4 | ( 0.6) | 5 | 0.92 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.24 |
| Polymyalgia rheumatica | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 3 | 0.43 |
| Soft tissue swelling | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 3 | 0.44 | 0 | | | |
| Joint effusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.29 | 2 | ( 0.2) | 2 | 0.17 |
| Muscle contracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.09 |
| Pain in jaw | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Torticollis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.15 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Back disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Coccydynia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Acquired claw toe | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Meniscopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Polyarthritis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Exostosis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Fibromyalgia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Fistula | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Intervertebral disc disorder | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.37 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.14 |
| Lumbar spinal stenosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Myositis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.15 |
| Osteopenia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Spinal pain | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.18 |
| Synovial cyst | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Arthropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Bone cyst | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Bone pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Cervical spinal stenosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Costochondritis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Diastasis recti abdominis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Dupuytren's contracture | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Facet joint syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Haemarthrosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Intervertebral disc degeneration | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Intervertebral disc space narrowing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.17 |
| Jaw disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Joint swelling | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.49 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Limb deformity | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Mastication disorder | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.28 |
| >=10 years | 0 | | | | 0 | | | |
| Muscle twitching | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Musculoskeletal pain | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Neuropathic arthropathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Nodal osteoarthritis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Osteochondritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Periostitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Psoriatic arthropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Rheumatoid arthritis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Sacroiliitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Scoliosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Spinal retrolisthesis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.17 |
| Tenosynovitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 6 | ( 0.8) | 7 | 1.07 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 3 | ( 0.3) | 3 | 0.32 |
| Tenosynovitis stenosans | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Vertebral osteophyte | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| General disorders and administration site conditions | | | | | | | | |
| All | | | | | | | | |
| <10 years | 72 | (10.5) | 126 | 23.69 | 66 | ( 9.2) | 96 | 16.94 |
| >=10 years | 127 | (10.6) | 187 | 22.12 | 108 | ( 9.3) | 165 | 17.55 |
| Pyrexia | | | | | | | | |
| <10 years | 9 | ( 1.3) | 10 | 1.74 | 14 | ( 1.9) | 15 | 2.77 |
| >=10 years | 23 | ( 1.9) | 23 | 2.48 | 23 | ( 2.0) | 24 | 2.62 |
| Fatigue | | | | | | | | |
| <10 years | 13 | ( 1.9) | 14 | 2.48 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 14 | ( 1.2) | 16 | 1.77 | 13 | ( 1.1) | 13 | 1.35 |
| Oedema peripheral | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.85 | 3 | ( 0.4) | 3 | 0.53 |
| >=10 years | 13 | ( 1.1) | 13 | 1.38 | 6 | ( 0.5) | 7 | 0.67 |
| Chest pain | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 12 | ( 1.0) | 12 | 1.30 | 3 | ( 0.3) | 3 | 0.26 |
| Injection site reaction | | | | | | | | |
| <10 years | 5 | ( 0.7) | 14 | 3.37 | 0 | | | |
| >=10 years | 10 | ( 0.9) | 15 | 2.11 | 6 | ( 0.5) | 8 | 0.86 |
| Vaccination site pain | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 8 | ( 0.7) | 10 | 1.28 | 6 | ( 0.5) | 6 | 0.75 |
| Malaise | | | | | | | | |
| <10 years | 5 | ( 0.7) | 7 | 1.03 | 2 | ( 0.3) | 3 | 0.42 |
| >=10 years | 8 | ( 0.7) | 8 | 0.91 | 10 | ( 0.9) | 13 | 1.43 |
| Pain | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.62 | 6 | ( 0.9) | 7 | 1.54 |
| >=10 years | 7 | ( 0.6) | 8 | 0.98 | 8 | ( 0.7) | 8 | 0.75 |
| Chest discomfort | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.51 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.60 | 2 | ( 0.2) | 2 | 0.23 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Asthenia | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.92 | 3 | ( 0.4) | 3 | 0.66 |
| >=10 years | 5 | ( 0.4) | 5 | 0.60 | 5 | ( 0.4) | 5 | 0.50 |
| Influenza like illness | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 4 | ( 0.3) | 5 | 0.60 | 1 | ( 0.1) | 1 | 0.09 |
| Medical device site reaction | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 4 | ( 0.3) | 6 | 0.69 | 0 | | | |
| Injection site pain | | | | | | | | |
| <10 years | 0 | | | | 5 | ( 0.7) | 5 | 1.01 |
| >=10 years | 3 | ( 0.3) | 3 | 0.43 | 7 | ( 0.6) | 25 | 2.35 |
| Injection site bruising | | | | | | | | |
| <10 years | 0 | | | | 5 | ( 0.7) | 5 | 0.79 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 0 | | | |
| Medical device site dermatitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 4 | 0.60 | 4 | ( 0.5) | 10 | 1.39 |
| >=10 years | 3 | ( 0.3) | 3 | 0.38 | 4 | ( 0.4) | 4 | 0.36 |
| Hunger | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.60 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 2 | ( 0.2) | 2 | 0.23 |
| Medical device site erythema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.15 |
| Injection site erythema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 4 | 0.58 | 4 | ( 0.4) | 4 | 0.36 |
| Injection site haematoma | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 8 | 1.97 |
| >=10 years | 2 | ( 0.2) | 6 | 0.87 | 0 | | | |
| Medical device site bruise | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.60 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 3 | 0.38 | 0 | | | |
| Medical device site pruritus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Feeling abnormal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 3 | 0.45 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 0 | | | |
| Injection site pruritus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 17 | 4.22 | 1 | ( 0.1) | 1 | 0.25 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Drug intolerance | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Gait disturbance | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.08 |
| Medical device site haemorrhage | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.09 |
| Application site pruritus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 8 | 1.19 |
| Inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.2) | 2 | 0.24 |
| Injection site haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.14 |
| Injection site rash | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Injection site swelling | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.14 |
| Peripheral swelling | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.58 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 1 | ( 0.1) | 2 | 0.29 | 2 | ( 0.2) | 2 | 0.30 |
| Multiple organ dysfunction syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 3 | ( 0.3) | 3 | 0.32 |
| Oedema due to renal disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vaccination site inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Vaccination site pruritus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Early satiety | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Vessel puncture site bruise | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Chills | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.51 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Implant site pruritus | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Injection site hypersensitivity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Injection site mass | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Medical device site eczema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Swelling | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Vaccination site reaction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Application site bruise | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Axillary pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Condition aggravated | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.23 |
| Death | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.17 |
| Facial pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Feeling hot | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Hernia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Injection site dermatitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Injection site hypertrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Injection site induration | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.38 |
| >=10 years | 0 | | | | 0 | | | |
| Injection site oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Injection site urticaria | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Localised oedema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Medical device site haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Medical device site hypersensitivity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Medical device site inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Medical device site pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 0 | | | | 0 | | | |
| Medical device site rash | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 0 | | | | 0 | | | |
| Non-cardiac chest pain | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 4 | 0.54 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.17 |
| Procedural failure | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Swelling face | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.23 |
| Systemic inflammatory response syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Thirst | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.66 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Vaccination site erythema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Xerosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.26 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Injury, poisoning and procedural complications | | | | | | | | |
| All | | | | | | | | |
| <10 years | 50 | ( 7.2) | 60 | 10.20 | 53 | ( 7.4) | 67 | 11.98 |
| >=10 years | 114 | ( 9.6) | 144 | 16.38 | 94 | ( 8.1) | 111 | 13.34 |
| Fall | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.79 | 3 | ( 0.4) | 4 | 0.65 |
| >=10 years | 14 | ( 1.2) | 14 | 1.47 | 7 | ( 0.6) | 7 | 0.77 |
| Vaccination complication | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.70 | 9 | ( 1.2) | 13 | 1.92 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 11 | ( 0.9) | 15 | 1.76 | 12 | ( 1.0) | 14 | 1.64 |
| Contusion | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.89 | 3 | ( 0.4) | 3 | 0.42 |
| >=10 years | 9 | ( 0.7) | 10 | 1.02 | 4 | ( 0.3) | 4 | 0.41 |
| Accidental overdose | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 2 | ( 0.3) | 3 | 0.74 |
| >=10 years | 6 | ( 0.5) | 6 | 0.75 | 1 | ( 0.1) | 1 | 0.15 |
| Skin laceration | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 6 | ( 0.5) | 6 | 0.69 | 0 | | | |
| Skin abrasion | | | | | | | | |
| <10 years | 3 | ( 0.4) | 5 | 0.72 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.67 | 4 | ( 0.3) | 4 | 0.52 |
| Ligament sprain | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.76 | 3 | ( 0.4) | 3 | 0.64 |
| >=10 years | 5 | ( 0.4) | 5 | 0.60 | 5 | ( 0.4) | 5 | 0.60 |
| Hand fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.54 | 1 | ( 0.1) | 1 | 0.08 |
| Overdose | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.64 |
| >=10 years | 4 | ( 0.3) | 4 | 0.52 | 0 | | | |
| Road traffic accident | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.45 | 1 | ( 0.1) | 1 | 0.08 |
| Rib fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 3 | ( 0.3) | 3 | 0.37 |
| Arthropod bite | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.40 |
| >=10 years | 3 | ( 0.3) | 3 | 0.44 | 1 | ( 0.1) | 1 | 0.15 |
| Joint injury | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.3) | 3 | 0.38 | 3 | ( 0.3) | 3 | 0.31 |
| Procedural pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 1 | ( 0.1) | 1 | 0.14 |
| Incorrect dose administered | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.38 |
| >=10 years | 3 | ( 0.3) | 3 | 0.44 | 3 | ( 0.3) | 5 | 0.73 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Limb injury | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 5 | ( 0.4) | 6 | 0.75 |
| Wound | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.51 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 3 | ( 0.3) | 3 | 0.38 |
| Medication error | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.15 |
| Tendon rupture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 1 | ( 0.1) | 1 | 0.14 |
| Foot fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 3 | 0.55 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 0 | | | |
| Tooth fracture | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.15 |
| Arthropod sting | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.14 |
| Back injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.08 |
| Upper limb fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Ankle fracture | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 3 | ( 0.3) | 3 | 0.25 |
| Hip fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Craniocerebral injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Face injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Subcutaneous haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |
| Thermal burn | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |
| Underdose | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.65 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.29 |
| Wrist fracture | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Accidental underdose | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Chillblains | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Extra dose administered | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| Subdural haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Wrong product administered | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.29 | 2 | ( 0.2) | 2 | 0.29 |
| Bone contusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.23 |
| Inflammation of wound | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Injury of conjunctiva | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Multiple injuries | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Muscle injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.29 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Neck injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Post procedural complication | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Post procedural haematuria | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Post procedural inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Radiation skin injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Cervical vertebral fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Eye injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Fibula fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Heat illness | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 3 | 0.55 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Injury | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Meniscus injury | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 3 | ( 0.4) | 3 | 0.52 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.17 |
| Post procedural haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Post procedural hypothyroidism | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Traumatic haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Animal bite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 3 | ( 0.3) | 3 | 0.32 |
| Burn oral cavity | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Burns first degree | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Concussion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.30 |
| Crush injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Deafness traumatic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Endotracheal intubation complication | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Epicondylitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Exposure to SARS-CoV-2 | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Facial bones fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Femoral neck fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Gun shot wound | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Head injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Humerus fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Intentional overdose | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Intentional product use issue | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Ligament rupture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.50 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Lower limb fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Muscle contusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Muscle strain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 4 | ( 0.3) | 4 | 0.47 |
| Penile contusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Periprocedural myocardial infarction | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Post procedural fistula | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Post procedural stroke | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Post procedural swelling | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.28 |
| >=10 years | 0 | | | | 0 | | | |
| Post-traumatic neck syndrome | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Procedural complication | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Product administration error | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Radius fracture | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Scar | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Scratch | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Seroma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Soft tissue injury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Spinal column injury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Spinal compression fracture | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Stab wound | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Sunburn | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Tendon injury | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Tibia fracture | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Wrong dose | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.29 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Nervous system disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 68 | ( 9.9) | 92 | 16.76 | 71 | ( 9.9) | 93 | 16.14 |
| >=10 years | 112 | ( 9.4) | 160 | 18.14 | 112 | ( 9.6) | 155 | 18.41 |
| Headache | | | | | | | | |
| <10 years | 24 | ( 3.5) | 31 | 5.74 | 24 | ( 3.4) | 33 | 5.67 |
| >=10 years | 33 | ( 2.8) | 42 | 5.31 | 30 | ( 2.6) | 34 | 4.12 |
| Dizziness | | | | | | | | |
| <10 years | 17 | ( 2.5) | 22 | 3.96 | 12 | ( 1.7) | 15 | 2.82 |
| >=10 years | 21 | ( 1.8) | 26 | 3.03 | 25 | ( 2.1) | 29 | 3.51 |
| Sciatica | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.53 | 6 | ( 0.8) | 6 | 0.96 |
| >=10 years | 10 | ( 0.8) | 10 | 1.21 | 6 | ( 0.5) | 7 | 0.79 |
| Carpal tunnel syndrome | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.65 | 0 | | | |
| >=10 years | 8 | ( 0.7) | 8 | 0.79 | 7 | ( 0.6) | 7 | 0.85 |
| Tremor | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.59 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 7 | ( 0.6) | 8 | 0.78 | 7 | ( 0.6) | 11 | 1.49 |
| Hypoaesthesia | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.65 | 4 | ( 0.6) | 5 | 0.80 |
| >=10 years | 6 | ( 0.5) | 9 | 0.93 | 5 | ( 0.4) | 5 | 0.60 |
| Neuropathy peripheral | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.65 | 3 | ( 0.4) | 3 | 0.54 |
| >=10 years | 4 | ( 0.3) | 4 | 0.45 | 6 | ( 0.5) | 6 | 0.63 |
| Syncope | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 4 | ( 0.3) | 4 | 0.40 | 0 | | | |
| Diabetic neuropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 3 | ( 0.4) | 3 | 0.52 |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 9 | ( 0.8) | 9 | 1.07 |
| Tension headache | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 3 | ( 0.3) | 4 | 0.40 | 0 | | | |
| Paraesthesia | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.83 | 5 | ( 0.7) | 5 | 0.91 |
| >=10 years | 3 | ( 0.2) | 4 | 0.33 | 7 | ( 0.6) | 7 | 0.90 |
| Neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.09 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Post herpetic neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Amnesia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 0 | | | |
| Dysgeusia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Cerebrovascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Memory impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.15 |
| Migraine | | | | | | | | |
| <10 years | 4 | ( 0.5) | 4 | 0.82 | 2 | ( 0.3) | 2 | 0.50 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.09 |
| Transient ischaemic attack | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.09 |
| Burning sensation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 2 | ( 0.2) | 2 | 0.23 |
| Autonomic nervous system imbalance | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Carotid artery aneurysm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Cervicobrachial syndrome | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Facial paralysis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Peripheral paralysis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Somnolence | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.09 |
| Thalamic infarction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Vascular headache | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Cerebral arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Vascular encephalopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Carotid artery stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Cerebral atrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Cluster headache | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Cognitive disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.15 |
| Cervical radiculopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Dizziness postural | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.15 |
| Neuroglycopenia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 3 | 0.27 |
| Presyncope | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 3 | ( 0.3) | 3 | 0.26 |
| Trigeminal neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Ageusia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Anosmia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Balance disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Basilar migraine | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Brain injury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Carotid arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Cerebral artery embolism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Cerebral haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Cerebral infarction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Cerebrovascular accident | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Dementia Alzheimer's type | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Disturbance in attention | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Essential tremor | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Facial nerve disorder | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hemiparesis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hypoglycaemic coma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hyporeflexia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Intracranial pressure increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Ischaemic stroke | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Lethargy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Loss of consciousness | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Lumbar radiculopathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 3 | ( 0.3) | 4 | 0.35 |
| Mental impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Meralgia paraesthetica | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Morton's neuralgia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Myelopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Ophthalmic migraine | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Orthostatic tremor | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Parkinsonian gait | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Piriformis syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Radiculopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Restless legs syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Sleep deficit | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Thrombotic stroke | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Vertebral artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| White matter lesion | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Eye disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 42 | ( 6.0) | 50 | 9.67 | 48 | ( 6.7) | 59 | 10.74 |
| >=10 years | 105 | ( 8.8) | 138 | 15.83 | 104 | ( 8.9) | 140 | 17.31 |
| Diabetic retinopathy | | | | | | | | |
| <10 years | 19 | ( 2.7) | 21 | 4.35 | 16 | ( 2.3) | 17 | 3.49 |
| >=10 years | 33 | ( 2.8) | 37 | 4.75 | 42 | ( 3.6) | 45 | 5.56 |
| Cataract | | | | | | | | |
| <10 years | 5 | ( 0.7) | 6 | 1.08 | 6 | ( 0.8) | 6 | 0.80 |
| >=10 years | 19 | ( 1.6) | 23 | 2.27 | 19 | ( 1.6) | 22 | 2.55 |
| Macular oedema | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.65 | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 6 | ( 0.5) | 6 | 0.75 | 3 | ( 0.3) | 3 | 0.32 |
| Retinopathy hypertensive | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 6 | ( 0.5) | 7 | 0.82 | 4 | ( 0.3) | 4 | 0.59 |
| Dry eye | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 4 | ( 0.6) | 4 | 0.66 |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 2 | ( 0.2) | 2 | 0.18 |
| Blepharitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.33 | 0 | | | |
| Retinal haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.44 | 0 | | | |
| Eye pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 1 | ( 0.1) | 1 | 0.09 |
| Vitreous detachment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 0 | | | |
| Glaucoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.2) | 3 | 0.24 | 2 | ( 0.2) | 2 | 0.23 |
| Ocular hyperaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.49 |
| >=10 years | 2 | ( 0.2) | 3 | 0.44 | 0 | | | |
| Diabetic retinal oedema | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.48 | 3 | ( 0.4) | 3 | 0.41 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 6 | ( 0.5) | 7 | 0.96 |
| Vitreous haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 2 | ( 0.2) | 2 | 0.24 |
| Eye inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.15 |
| Age-related macular degeneration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Conjunctival haemorrhage | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Dry age-related macular degeneration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Epiretinal membrane | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.23 |
| Eye irritation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Lacrimation increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Myopia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Retinal exudates | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.30 |
| Non-proliferative retinopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.29 | 2 | ( 0.2) | 2 | 0.29 |
| Vision blurred | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.54 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.3) | 3 | 0.38 |
| Diplopia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Presbyopia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.29 |
| Retinal deposits | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Retinal drusen | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |
| Retinal scar | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Amaurosis fugax | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Angle closure glaucoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Arteriosclerotic retinopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Conjunctival hyperaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Maculopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Ocular hypertension | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Visual impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 10 | 1.42 |
| Vitreous opacities | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Acquired epiblepharon | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Asthenopia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Astigmatism | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.28 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.29 |
| Conjunctival erosion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Conjunctivitis allergic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.17 | 0 | | | |
| Optic disc vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Post thrombotic retinopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Posterior capsule opacification | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Retinal aneurysm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Retinal tear | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Cataract nuclear | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Chorioretinal atrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Conjunctival suffusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Corneal bleeding | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Corneal erosion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Cystoid macular oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Dacryoadenitis acquired | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Eye discharge | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Eye pruritus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.49 |
| >=10 years | 0 | | | | 0 | | | |
| Eyelid oedema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Hypermetropia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Macular degeneration | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.23 |
| Macular hole | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Meibomianitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Normal tension glaucoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Ocular ischaemic syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Open angle glaucoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.30 |
| Ophthalmic vein thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Optic disc haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Photophobia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Retinal artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Retinal degeneration | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Retinal detachment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.24 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Retinal vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Retinal vein occlusion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Retinopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Scintillating scotoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Uveitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Visual acuity reduced | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Vitreous degeneration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Vitreous floaters | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Metabolism and nutrition disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 46 | ( 6.7) | 62 | 10.45 | 57 | ( 8.0) | 72 | 12.60 |
| >=10 years | 78 | ( 6.5) | 91 | 9.80 | 68 | ( 5.9) | 86 | 9.70 |
| Dyslipidaemia | | | | | | | | |
| <10 years | 8 | ( 1.2) | 9 | 1.68 | 10 | ( 1.4) | 10 | 2.04 |
| >=10 years | 13 | ( 1.1) | 13 | 1.51 | 7 | ( 0.6) | 7 | 0.91 |
| Hypoglycaemia | | | | | | | | |
| <10 years | 4 | ( 0.6) | 9 | 1.93 | 9 | ( 1.2) | 17 | 2.69 |
| >=10 years | 9 | ( 0.8) | 10 | 1.27 | 11 | ( 0.9) | 19 | 2.28 |
| Hyperlipidaemia | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.83 | 8 | ( 1.1) | 8 | 1.32 |
| >=10 years | 9 | ( 0.8) | 9 | 0.99 | 5 | ( 0.4) | 5 | 0.55 |
| Vitamin D deficiency | | | | | | | | |
| <10 years | 7 | ( 1.0) | 7 | 1.00 | 8 | ( 1.1) | 8 | 1.29 |
| >=10 years | 9 | ( 0.7) | 9 | 0.80 | 4 | ( 0.4) | 4 | 0.35 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hyperkalaemia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 3 | ( 0.4) | 3 | 0.54 |
| >=10 years | 6 | ( 0.5) | 7 | 0.77 | 7 | ( 0.6) | 7 | 0.85 |
| Hypertriglyceridaemia | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.60 | 6 | ( 0.8) | 6 | 1.05 |
| >=10 years | 6 | ( 0.5) | 6 | 0.68 | 2 | ( 0.2) | 2 | 0.29 |
| Hyperglycaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 5 | ( 0.7) | 5 | 0.80 |
| >=10 years | 5 | ( 0.4) | 6 | 0.74 | 9 | ( 0.8) | 9 | 1.20 |
| Vitamin B12 deficiency | | | | | | | | |
| <10 years | 7 | ( 1.0) | 7 | 0.99 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 4 | ( 0.3) | 4 | 0.32 | 0 | | | |
| Decreased appetite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 5 | ( 0.4) | 5 | 0.49 |
| Fluid retention | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Hypercholesterolaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 3 | ( 0.4) | 3 | 0.66 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Hypokalaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.09 |
| Hyperuricaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.08 |
| Iron deficiency | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.43 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.08 |
| Gout | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 3 | 0.25 | 5 | ( 0.4) | 6 | 0.51 |
| Increased appetite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.50 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 4 | ( 0.3) | 5 | 0.61 |
| Abnormal weight gain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Dehydration | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.09 |
| Hypoalbuminaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hyponatraemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.26 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |
| Folate deficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Magnesium deficiency | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Malnutrition | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Zinc deficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Obesity | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Appetite disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.18 |
| Diabetes mellitus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Diabetes mellitus inadequate control | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Electrolyte imbalance | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Food craving | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Hyperammonaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hypercalcaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Hypernatraemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Insulin resistance | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Lactic acidosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Lipomatosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Metabolic acidosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Metabolic disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Vitamin B complex deficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 42 | ( 6.1) | 57 | 9.91 | 39 | ( 5.4) | 43 | 7.25 |
| >=10 years | 69 | ( 5.8) | 94 | 10.88 | 62 | ( 5.3) | 81 | 9.30 |
| Cough | | | | | | | | |
| <10 years | 8 | ( 1.2) | 8 | 1.38 | 9 | ( 1.2) | 9 | 1.35 |
| >=10 years | 15 | ( 1.3) | 16 | 1.76 | 11 | ( 1.0) | 12 | 1.40 |
| Rhinorrhoea | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.37 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 8 | ( 0.7) | 11 | 1.29 | 5 | ( 0.4) | 5 | 0.49 |
| Oropharyngeal pain | | | | | | | | |
| <10 years | 11 | ( 1.6) | 12 | 1.97 | 3 | ( 0.4) | 4 | 0.56 |
| >=10 years | 8 | ( 0.7) | 9 | 0.93 | 13 | ( 1.1) | 14 | 1.74 |
| Nasal congestion | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 3 | ( 0.4) | 3 | 0.44 | 3 | ( 0.4) | 3 | 0.41 |
| >=10 years | 7 | ( 0.6) | 7 | 0.70 | 1 | ( 0.1) | 1 | 0.08 |
| Dyspnoea | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.64 | 4 | ( 0.5) | 4 | 0.77 |
| >=10 years | 6 | ( 0.5) | 6 | 0.68 | 9 | ( 0.8) | 10 | 1.12 |
| Epistaxis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 2 | 0.28 |
| >=10 years | 4 | ( 0.3) | 8 | 1.18 | 1 | ( 0.1) | 2 | 0.30 |
| Sleep apnoea syndrome | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.53 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.40 | 0 | | | |
| Productive cough | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.3) | 3 | 0.38 | 1 | ( 0.1) | 1 | 0.14 |
| Chronic obstructive pulmonary disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.38 | 1 | ( 0.1) | 1 | 0.09 |
| Asthma | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.55 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 1 | ( 0.1) | 1 | 0.15 |
| Nasal septum deviation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.15 |
| Sneezing | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Pulmonary fibrosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 3 | 0.31 | 0 | | | |
| Respiratory disorder | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.52 | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 3 | ( 0.3) | 3 | 0.39 |
| Acute respiratory failure | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.09 |
| Nasal obstruction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Respiratory failure | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Bronchospasm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Sinus congestion | | | | | | | | |
| <10 years | 3 | ( 0.4) | 4 | 0.70 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.09 |
| Emphysema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Pulmonary hypertension | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Sinus pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.30 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Rhinitis allergic | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.50 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 3 | ( 0.3) | 7 | 0.73 |
| Acquired diaphragmatic eventration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Dyspnoea exertional | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Laryngeal cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Pulmonary embolism | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Pulmonary mass | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.63 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Upper-airway cough syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Acute pulmonary oedema | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Allergic bronchitis | | | | | | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Allergic cough | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Aphonia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Bronchiectasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Bronchitis chronic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Dry throat | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Dysphonia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.29 |
| Haemoptysis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Increased viscosity of upper respiratory secretion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Interstitial lung disease | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Lung disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Nasal dryness | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Nasal turbinate hypertrophy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Paranasal cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.30 |
| Paranasal sinus discomfort | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Pleural disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Pleural effusion | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.17 |
| Pleurisy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.26 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pleuritic pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Respiratory tract inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Throat irritation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Upper respiratory tract inflammation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Skin and subcutaneous tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 35 | ( 5.1) | 38 | 6.24 | 41 | ( 5.7) | 50 | 8.17 |
| >=10 years | 64 | ( 5.4) | 69 | 7.66 | 63 | ( 5.4) | 73 | 8.02 |
| Rash | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.90 | 3 | ( 0.4) | 3 | 0.41 |
| >=10 years | 6 | ( 0.5) | 6 | 0.68 | 8 | ( 0.7) | 9 | 0.90 |
| Pruritus | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 6 | ( 0.5) | 6 | 0.68 | 9 | ( 0.8) | 9 | 1.08 |
| Eczema | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.66 | 3 | ( 0.4) | 3 | 0.52 |
| >=10 years | 6 | ( 0.5) | 6 | 0.62 | 3 | ( 0.3) | 3 | 0.44 |
| Urticaria | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 7 | ( 1.0) | 7 | 1.06 |
| >=10 years | 5 | ( 0.4) | 5 | 0.67 | 2 | ( 0.2) | 2 | 0.18 |
| Hyperhidrosis | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.68 | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.52 | 5 | ( 0.4) | 5 | 0.55 |
| Skin ulcer | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.50 |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 3 | ( 0.3) | 3 | 0.38 |
| Cold sweat | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 2 | ( 0.2) | 2 | 0.24 |
| Alopecia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.37 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 3 | ( 0.2) | 3 | 0.31 | 1 | ( 0.1) | 1 | 0.09 |
| Dermatitis contact | | | | | | | | |
| <10 years | 2 | ( 0.3) | 3 | 0.45 | 3 | ( 0.4) | 3 | 0.53 |
| >=10 years | 3 | ( 0.2) | 3 | 0.25 | 5 | ( 0.4) | 5 | 0.50 |
| Miliaria | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 2 | ( 0.2) | 2 | 0.18 |
| Acne | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 0 | | | |
| Hyperkeratosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.15 |
| Night sweats | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Dermatitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 3 | ( 0.4) | 4 | 0.77 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 3 | ( 0.3) | 3 | 0.32 |
| Ingrowing nail | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 2 | ( 0.2) | 2 | 0.18 |
| Dry skin | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 3 | ( 0.4) | 3 | 0.51 |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.08 |
| Rash papular | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Decubitus ulcer | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Ecchymosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.09 |
| Skin odour abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Intertrigo | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Umbilical haematoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Dermatitis allergic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Angioedema | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Lipodystrophy acquired | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Myxoid cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Skin fissures | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Skin irritation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.08 |
| Skin lesion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Urticaria contact | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Actinic keratosis | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Alopecia areata | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Asteatosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Blister | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 0 | | | | 0 | | | |
| Cold urticaria | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Dermal cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 3 | ( 0.3) | 3 | 0.32 |
| Diabetic foot | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.17 |
| Drug eruption | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Erythema | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.23 |
| Granuloma annulare | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Haemorrhage subcutaneous | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Hidradenitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Lentigo | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Leukoplakia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lipohypertrophy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.24 |
| Livedo reticularis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Macule | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Nail bed inflammation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Neurodermatitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Pruritus allergic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Psoriasis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Purpura | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Rash erythematous | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Rash maculo-papular | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Seborrhoea | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Skin discolouration | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Skin exfoliation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Skin reaction | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Urticaria thermal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Cardiac disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 32 | ( 4.7) | 45 | 7.11 | 25 | ( 3.5) | 36 | 6.38 |
| >=10 years | 54 | ( 4.5) | 79 | 7.90 | 54 | ( 4.7) | 73 | 7.34 |
| Acute myocardial infarction | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 7 | ( 0.6) | 7 | 0.76 | 7 | ( 0.6) | 7 | 0.73 |
| Atrial fibrillation | | | | | | | | |
| <10 years | 5 | ( 0.7) | 5 | 0.73 | 3 | ( 0.4) | 3 | 0.41 |
| >=10 years | 7 | ( 0.6) | 8 | 0.73 | 3 | ( 0.3) | 3 | 0.33 |
| Coronary artery disease | | | | | | | | |
| <10 years | 6 | ( 0.9) | 6 | 0.87 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 6 | ( 0.5) | 6 | 0.62 | 9 | ( 0.8) | 9 | 0.89 |
| Myocardial infarction | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 5 | ( 0.4) | 5 | 0.61 | 3 | ( 0.3) | 3 | 0.26 |
| Cardiac failure | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.44 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.47 | 2 | ( 0.2) | 3 | 0.38 |
| Angina pectoris | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.47 | 4 | ( 0.3) | 4 | 0.40 |
| Cardiac failure congestive | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 3 | 0.75 |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 0 | | | |
| Palpitations | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.44 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 4 | ( 0.3) | 4 | 0.41 |
| Supraventricular extrasystoles | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 2 | ( 0.2) | 2 | 0.17 |
| Myocardial ischaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.17 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Arrhythmia | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.09 |
| Angina unstable | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.09 |
| Cardiac failure chronic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.09 |
| Coronary artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 0 | | | |
| Left ventricular hypertrophy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 2 | ( 0.2) | 2 | 0.24 |
| Ventricular extrasystoles | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.45 | 1 | ( 0.1) | 2 | 0.27 |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 1 | ( 0.1) | 1 | 0.09 |
| Cardiac flutter | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Supraventricular tachycardia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Atrioventricular block first degree | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Cardio-respiratory arrest | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Aortic valve sclerosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Left atrial enlargement | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Arteriosclerosis coronary artery | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Bundle branch block left | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.15 |
| Mitral valve incompetence | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.17 |
| Tachycardia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 4 | ( 0.6) | 4 | 0.88 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 3 | ( 0.3) | 3 | 0.26 |
| Acute coronary syndrome | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.43 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Atrial flutter | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Atrial thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Bundle branch block right | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 3 | 0.42 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 4 | ( 0.3) | 4 | 0.46 |
| Cardiac ventricular thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Diastolic dysfunction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Left atrial dilatation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Left ventricular dysfunction | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Pericardial effusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Tricuspid valve incompetence | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 3 | ( 0.3) | 3 | 0.26 |
| Aortic valve calcification | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Aortic valve incompetence | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Atrial enlargement | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Atrioventricular block complete | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Bradycardia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.41 |
| >=10 years | 0 | | | | 0 | | | |
| Cardiac arrest | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.17 |
| Cardiac dysfunction | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Cardiac failure acute | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Cardiac perfusion defect | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.30 |
| Chronic coronary syndrome | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Coronary artery stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Mitral valve stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pericarditis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Sinus arrhythmia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Sinus bradycardia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 3 | ( 0.3) | 3 | 0.32 |
| Sinus tachycardia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Subendocardial ischaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Ventricular arrhythmia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Ventricular tachycardia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Investigations | | | | | | | | |
| All | | | | | | | | |
| <10 years | 33 | ( 4.8) | 35 | 6.39 | 31 | ( 4.3) | 35 | 5.44 |
| >=10 years | 47 | ( 3.9) | 59 | 6.48 | 35 | ( 3.0) | 38 | 4.78 |
| Weight increased | | | | | | | | |
| <10 years | 6 | ( 0.9) | 6 | 1.22 | 11 | ( 1.5) | 11 | 1.63 |
| >=10 years | 13 | ( 1.1) | 13 | 1.38 | 7 | ( 0.6) | 7 | 0.97 |
| Blood creatinine increased | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.53 | 0 | | | |
| >=10 years | 5 | ( 0.4) | 5 | 0.73 | 0 | | | |
| SARS-CoV-2 test positive | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.76 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.43 | 0 | | | |
| Alanine aminotransferase increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 0 | | | |
| Blood pressure increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 3 | ( 0.3) | 3 | 0.32 |
| Weight decreased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.2) | 3 | 0.25 | 0 | | | |
| Blood alkaline phosphatase increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 0 | | | |
| Liver function test increased | | | | | | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.08 |
| Prostatic specific antigen increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Blood cholesterol increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 0 | | | |
| Arthroscopy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Aspartate aminotransferase increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.09 |
| Occult blood | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Catheterisation cardiac | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Eosinophil count increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Liver function test abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 2 | 0.29 |
| Blood immunoglobulin E increased | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.28 | 3 | ( 0.4) | 3 | 0.40 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Blood triglycerides increased | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.41 | 3 | ( 0.4) | 3 | 0.41 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Blood urine present | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 3 | 0.24 | 1 | ( 0.1) | 1 | 0.15 |
| Bone density decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Electrocardiogram ST segment abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hepatic enzyme increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| QRS axis abnormal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Body temperature increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| International normalised ratio abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| International normalised ratio decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| International normalised ratio increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 2 | 0.17 | 0 | | | |
| Red blood cell count decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Amylase increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Antinuclear antibody positive | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Blood creatine increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood creatine phosphokinase increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood glucose decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Blood glucose fluctuation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood glucose increased | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Blood potassium increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Blood pressure decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Breath sounds abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Carbohydrate antigen 19-9 increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Cardiac murmur | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Cardiac stress test abnormal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Ejection fraction decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Electrocardiogram abnormal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Electrocardiogram P wave biphasic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Electrocardiogram repolarisation abnormality | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Electrocardiogram ST segment depression | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Electrocardiogram T wave inversion | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Free fatty acids increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Glomerular filtration rate decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Glycosylated haemoglobin increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 2 | 0.27 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Grip strength decreased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Haematocrit increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Haemoglobin decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Haemoglobin increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Intraocular pressure increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Lipase increased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Lipids increased | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Low density lipoprotein increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Monocyte count decreased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Monofilament pressure perception test | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Platelet count decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.29 |
| Thyroid function test abnormal | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Transaminases increased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Transferrin saturation decreased | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Vitamin D decreased | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Vascular disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 27 | ( 4.0) | 27 | 4.78 | 32 | ( 4.5) | 37 | 6.42 |
| >=10 years | 46 | ( 3.8) | 55 | 5.87 | 44 | ( 3.8) | 58 | 6.69 |
| Hypertension | | | | | | | | |
| <10 years | 12 | ( 1.8) | 12 | 2.17 | 17 | ( 2.4) | 18 | 3.15 |
| >=10 years | 20 | ( 1.7) | 20 | 2.22 | 18 | ( 1.5) | 22 | 2.62 |
| Hypotension | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.44 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 2 | ( 0.2) | 2 | 0.23 |
| Peripheral arterial occlusive disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.2) | 4 | 0.39 | 1 | ( 0.1) | 1 | 0.09 |
| Superficial vein thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.24 | 0 | | | |
| Orthostatic hypotension | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 0 | | | |
| Haematoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.23 |
| Peripheral artery stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 5 | 0.60 | 0 | | | |
| Peripheral venous disease | | | | | | | | |
| <10 years | 0 | | | | 3 | ( 0.4) | 3 | 0.52 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Arteriosclerosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.38 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 5 | ( 0.4) | 5 | 0.55 |
| Aortic arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 2 | ( 0.2) | 2 | 0.29 |
| Deep vein thrombosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Diabetic vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.29 |
| Blood pressure inadequately controlled | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.17 |
| Aortic stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Brachiocephalic arteriosclerosis | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Hypertensive urgency | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 3 | 0.32 |
| Peripheral artery occlusion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Peripheral coldness | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Peripheral vascular disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Varicose vein | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.17 |
| Aneurysm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Aortic aneurysm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Aortic dilatation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Arterial insufficiency | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood pressure fluctuation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Flushing | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Hot flush | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Hypertensive crisis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.26 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 3 | 0.44 |
| Iliac artery stenosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Intermittent claudication | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Macroangiopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Neovascularisation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Peripheral artery aneurysm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Peripheral ischaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Phlebitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Thrombophlebitis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Thrombosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Varicose ulceration | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Venous stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Renal and urinary disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 17 | ( 2.4) | 22 | 3.99 | 18 | ( 2.5) | 25 | 3.93 |
| >=10 years | 34 | ( 2.9) | 40 | 4.50 | 33 | ( 2.9) | 39 | 4.10 |
| Renal impairment | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 4 | ( 0.3) | 4 | 0.46 | 3 | ( 0.3) | 3 | 0.26 |
| Nephrolithiasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 3 | 0.51 |
| >=10 years | 4 | ( 0.3) | 4 | 0.33 | 2 | ( 0.2) | 3 | 0.38 |
| Pollakiuria | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.50 | 0 | | | |
| >=10 years | 3 | ( 0.3) | 3 | 0.38 | 2 | ( 0.2) | 2 | 0.18 |
| Acute kidney injury | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 3 | ( 0.3) | 3 | 0.26 |
| Renal cyst | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.76 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 3 | ( 0.3) | 3 | 0.32 |
| Dysuria | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 3 | ( 0.2) | 4 | 0.39 | 3 | ( 0.3) | 3 | 0.33 |
| Diabetic nephropathy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.29 |
| Urine odour abnormal | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 1 | ( 0.1) | 1 | 0.14 |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Chronic kidney disease | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.40 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.29 | 4 | ( 0.3) | 4 | 0.41 |
| Nephrotic syndrome | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Polyuria | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.08 |
| Chromaturia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Ureterolithiasis | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.09 |
| Haematuria | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 2 | 0.29 | 4 | ( 0.3) | 4 | 0.41 |
| Hypertonic bladder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Renal pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Urinary tract disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Microalbuminuria | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Nocturia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.18 |
| Pyelocaliectasis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Renal colic | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.38 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.14 |
| Bladder mass | | | | | | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Bladder prolapse | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Calculus urinary | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Cystitis haemorrhagic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Hydrocalyx | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Hydronephrosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Micturition urgency | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Nephropathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Proteinuria | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Renal failure | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Renal mass | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Strangury | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Stress urinary incontinence | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Urethral stenosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Urinary incontinence | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 3 | 0.41 |
| >=10 years | 0 | | | | 0 | | | |
| Urinary retention | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.17 |
| Urinary tract inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Urinary tract obstruction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Psychiatric disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 14 | ( 2.0) | 15 | 2.60 | 9 | ( 1.2) | 9 | 1.56 |
| >=10 years | 22 | ( 1.8) | 25 | 2.57 | 28 | ( 2.4) | 30 | 3.54 |
| Insomnia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.30 | 0 | | | |
| >=10 years | 8 | ( 0.7) | 8 | 0.92 | 6 | ( 0.5) | 7 | 0.79 |
| Depression | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.43 | 5 | ( 0.7) | 5 | 0.79 |
| >=10 years | 5 | ( 0.4) | 5 | 0.54 | 4 | ( 0.3) | 4 | 0.52 |
| Sleep disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 3 | ( 0.2) | 3 | 0.25 | 4 | ( 0.3) | 4 | 0.58 |
| Anxiety | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.55 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 6 | ( 0.5) | 6 | 0.51 |
| Adjustment disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Mental status changes | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Adjustment disorder with mixed anxiety and depressed mood | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Disorientation | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Irritability | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Stress | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Nightmare | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Adjustment disorder with depressed mood | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Affect lability | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Agitation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Anxiety disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Bruxism | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Depressed mood | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Drug abuse | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Drug dependence | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Emotional distress | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Fear | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.30 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Listless | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Major depression | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Mixed anxiety and depressive disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Mood swings | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Persistent depressive disorder | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Phobia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Post-traumatic stress disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Blood and lymphatic system disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 12 | ( 1.7) | 14 | 2.87 | 13 | ( 1.8) | 13 | 2.24 |
| >=10 years | 21 | ( 1.7) | 21 | 2.17 | 17 | ( 1.5) | 17 | 1.83 |
| Anaemia | | | | | | | | |
| <10 years | 8 | ( 1.1) | 10 | 2.19 | 4 | ( 0.5) | 4 | 0.55 |
| >=10 years | 11 | ( 0.9) | 11 | 1.09 | 10 | ( 0.9) | 10 | 1.17 |
| Iron deficiency anaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 2 | ( 0.2) | 2 | 0.17 |
| Lymphadenopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Blood loss anaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.17 |
| Eosinophilia | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.2) | 2 | 0.24 |
| Lymphadenopathy mediastinal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Splenomegaly | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Polycythaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Thrombocytopenia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Hypochromic anaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Leukocytosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.27 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Leukopenia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Normocytic anaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Pancytopenia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Thrombocytosis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 0 | | | | 0 | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | | | | | |
| All | | | | | | | | |
| <10 years | 12 | ( 1.7) | 15 | 2.81 | 6 | ( 0.8) | 11 | 1.60 |
| >=10 years | 19 | ( 1.6) | 24 | 2.40 | 21 | ( 1.8) | 29 | 3.14 |
| Adenocarcinoma pancreas | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 0 | | | |

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Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Colon adenoma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.22 | 0 | | | |
| Pancreatic neoplasm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Metastases to liver | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 1 | ( 0.1) | 1 | 0.08 |
| Chronic myeloid leukaemia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Gastric cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Eye naevus | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.28 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Osteoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Bladder cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Colorectal cancer | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Invasive ductal breast carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Invasive lobular breast carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Lipoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Pancreatic carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Renal neoplasm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Squamous cell carcinoma of skin | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Basal cell carcinoma | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.28 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Glioblastoma multiforme | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Prostate cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Seborrhoeic keratosis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.30 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Acrochordon | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Adenocarcinoma of colon | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Adrenal adenoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.29 |
| Benign renal neoplasm | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Bladder papilloma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Bowen's disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Breast cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Breast cancer metastatic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Colon cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Colon cancer stage II | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Dysplastic naevus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Endometrial adenocarcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Gastrointestinal tract adenoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Haemangioma of liver | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Hepatocellular carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Invasive breast carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Lung adenocarcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.29 |
| Lung cancer metastatic | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Lymphangioma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Malignant melanoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Malignant melanoma in situ | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Malignant peritoneal neoplasm | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=10 years | 0 | | | | 0 | | | |
| Metastases to bone marrow | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Metastases to lymph nodes | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Myxoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Neoplasm skin | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Oral fibroma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Ovarian cancer metastatic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Pancreatic carcinoma metastatic | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Prostatic adenoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Renal cell carcinoma | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Renal hamartoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Salivary gland neoplasm | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Skin papilloma | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Small cell lung cancer | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.26 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Small intestine neuroendocrine tumour | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Uterine cancer | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Uterine leiomyoma | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.24 |
| Reproductive system and breast disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 10 | ( 1.4) | 10 | 1.92 | 10 | ( 1.4) | 12 | 1.98 |
| >=10 years | 19 | ( 1.6) | 19 | 1.88 | 13 | ( 1.1) | 15 | 1.47 |
| Benign prostatic hyperplasia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 5 | ( 0.4) | 5 | 0.54 | 2 | ( 0.2) | 2 | 0.24 |
| Erectile dysfunction | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.29 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 3 | ( 0.3) | 3 | 0.31 | 0 | | | |
| Uterine polyp | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Prostatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Prostatic calcification | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Atrophic vulvovaginitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Breast mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Menopausal symptoms | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Ovarian cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Pruritus genital | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.23 |
| Uterine prolapse | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.08 |
| Vulvovaginal pruritus | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.09 |
| Breast pain | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Cervical polyp | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Colpocele | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Dysmenorrhoea | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Ejaculation failure | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Galactorrhoea | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Genital prolapse | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Intermenstrual bleeding | | | | | | | | |
| <10 years | 2 | ( 0.3) | 2 | 0.50 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Menopausal disorder | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Menstruation delayed | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Menstruation irregular | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Pelvic discomfort | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Penile rash | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.18 |
| Testicular cyst | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Uterine enlargement | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Vaginal discharge | | | | | | | | |
| <10 years | 0 | | | | 2 | ( 0.3) | 2 | 0.38 |
| >=10 years | 0 | | | | 0 | | | |
| Vaginal haemorrhage | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 2 | ( 0.2) | 2 | 0.17 |
| Vulvovaginal dryness | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Ear and labyrinth disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 11 | ( 1.6) | 11 | 1.85 | 5 | ( 0.7) | 5 | 0.91 |
| >=10 years | 15 | ( 1.3) | 18 | 1.79 | 17 | ( 1.5) | 18 | 2.04 |
| Vertigo | | | | | | | | |
| <10 years | 3 | ( 0.4) | 3 | 0.44 | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 7 | ( 0.6) | 8 | 0.91 | 7 | ( 0.6) | 8 | 0.88 |
| Deafness bilateral | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Vertigo positional | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Cerumen impaction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.15 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Ear pain | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.76 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 1 | ( 0.1) | 1 | 0.14 |
| External ear pain | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Hypoacusis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.22 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 3 | ( 0.3) | 3 | 0.26 |
| Ear inflammation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Tinnitus | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 2 | ( 0.2) | 2 | 0.23 |
| Deafness unilateral | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Ear discomfort | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Eustachian tube dysfunction | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Meniere's disease | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Middle ear inflammation | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Motion sickness | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Presbyacusis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Hepatobiliary disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 8 | ( 1.2) | 12 | 2.08 | 14 | ( 1.9) | 17 | 2.99 |
| >=10 years | 11 | ( 0.9) | 13 | 1.39 | 7 | ( 0.6) | 8 | 0.92 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hepatic steatosis | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.69 | 7 | ( 1.0) | 7 | 1.17 |
| >=10 years | 4 | ( 0.3) | 4 | 0.33 | 2 | ( 0.2) | 2 | 0.23 |
| Cholelithiasis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 2 | ( 0.2) | 2 | 0.16 | 0 | | | |
| Alcoholic liver disease | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Gallbladder polyp | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Cholecystitis chronic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hepatomegaly | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hyperplastic cholecystopathy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hepatic mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Gallbladder cholesterolosis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Bile duct stone | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.17 |
| Biliary colic | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Biliary dyskinesia | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Cholecystitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Hepatic cirrhosis | | | | | | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Hepatic cyst | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Hepatic function abnormal | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 0 | | | | 0 | | | |
| Hypertransaminasaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 2 | 0.30 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Liver disorder | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.15 |
| Non-alcoholic steatohepatitis | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Nonalcoholic fatty liver disease | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Steatohepatitis | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Immune system disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 5 | ( 0.7) | 6 | 0.94 | 6 | ( 0.9) | 7 | 1.34 |
| >=10 years | 7 | ( 0.6) | 7 | 0.83 | 9 | ( 0.8) | 9 | 1.13 |
| Seasonal allergy | | | | | | | | |
| <10 years | 4 | ( 0.6) | 4 | 0.65 | 3 | ( 0.4) | 3 | 0.55 |
| >=10 years | 4 | ( 0.3) | 4 | 0.39 | 5 | ( 0.4) | 5 | 0.62 |
| Anaphylactic reaction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.14 |
| Drug hypersensitivity | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hypersensitivity | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Allergy to arthropod bite | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 1 | ( 0.2) | 1 | 0.27 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Allergy to arthropod sting | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Food allergy | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Immunisation reaction | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 2 | 0.28 |
| >=10 years | 0 | | | | 0 | | | |
| Endocrine disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 0 | | | | 9 | ( 1.2) | 9 | 1.45 |
| >=10 years | 6 | ( 0.5) | 6 | 0.62 | 9 | ( 0.8) | 9 | 1.00 |
| Hypothyroidism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 3 | ( 0.3) | 3 | 0.31 |
| Thyroid mass | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 2 | ( 0.2) | 2 | 0.17 | 2 | ( 0.2) | 2 | 0.23 |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hypogonadism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Autoimmune thyroiditis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Adrenal mass | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Adrenocortical insufficiency acute | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Goitre | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Hyperplasia adrenal | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Hyperprolactinaemia | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Hyperthyroidism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Inappropriate antidiuretic hormone secretion | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Secondary hypogonadism | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Congenital, familial and genetic disorders | | | | | | | | |
| All | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 3 | ( 0.4) | 3 | 0.51 |
| >=10 years | 5 | ( 0.4) | 5 | 0.60 | 2 | ( 0.2) | 2 | 0.17 |
| Type V hyperlipidaemia | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 2 | ( 0.2) | 2 | 0.23 | 0 | | | |
| Cystic fibrosis lung | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| Corneal dystrophy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Hydrocele | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Atrial septal defect | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Congenital syphilitic osteochondritis | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Hypertrophic cardiomyopathy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |
| Myotonic dystrophy | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=10 years | 0 | | | | 0 | | | |

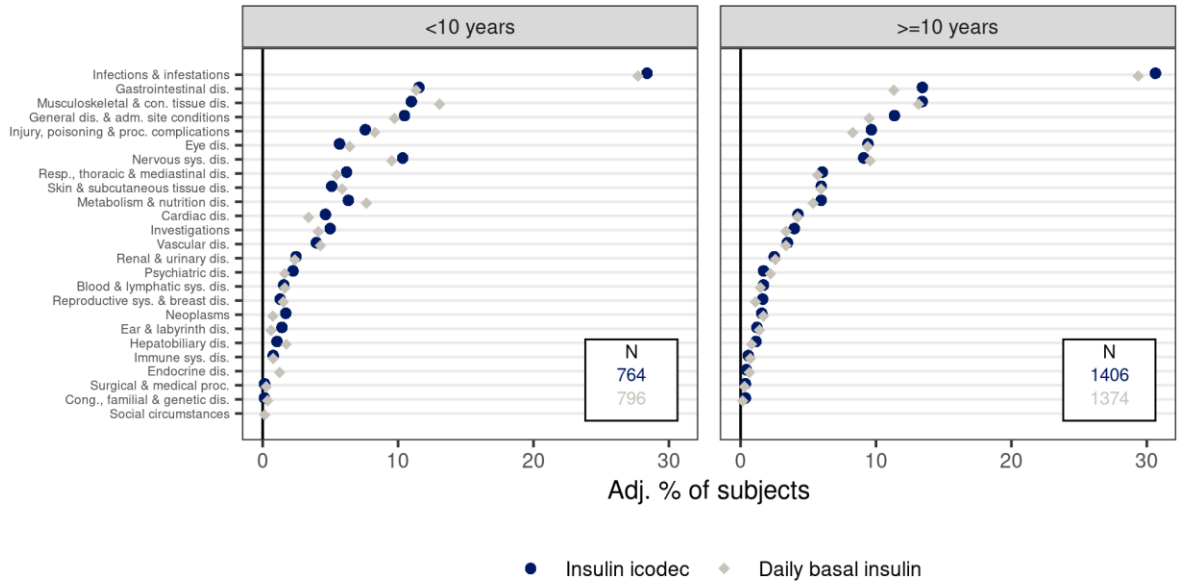
%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by diabetes duration, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Surgical and medical procedures | | | | | | | | |
| All | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.39 |
| >=10 years | 3 | ( 0.3) | 3 | 0.37 | 4 | ( 0.3) | 4 | 0.40 |
| Shoulder operation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Tooth extraction | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| Cardiac pacemaker replacement | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 1 | ( 0.1) | 1 | 0.08 | 0 | | | |
| Knee operation | | | | | | | | |
| <10 years | 1 | ( 0.1) | 1 | 0.15 | 0 | | | |
| >=10 years | 0 | | | | 0 | | | |
| Large intestinal polypectomy | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.09 |
| Removal of foreign body | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| >=10 years | 0 | | | | 0 | | | |
| Skin neoplasm excision | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Spinal operation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.08 |
| Toe amputation | | | | | | | | |
| <10 years | 0 | | | | 0 | | | |
| >=10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.14 |
| Social circumstances | | | | | | | | |
| All | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |
| Menopause | | | | | | | | |
| <10 years | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=10 years | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

## 7.7.53 Adverse events by diabetes duration and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

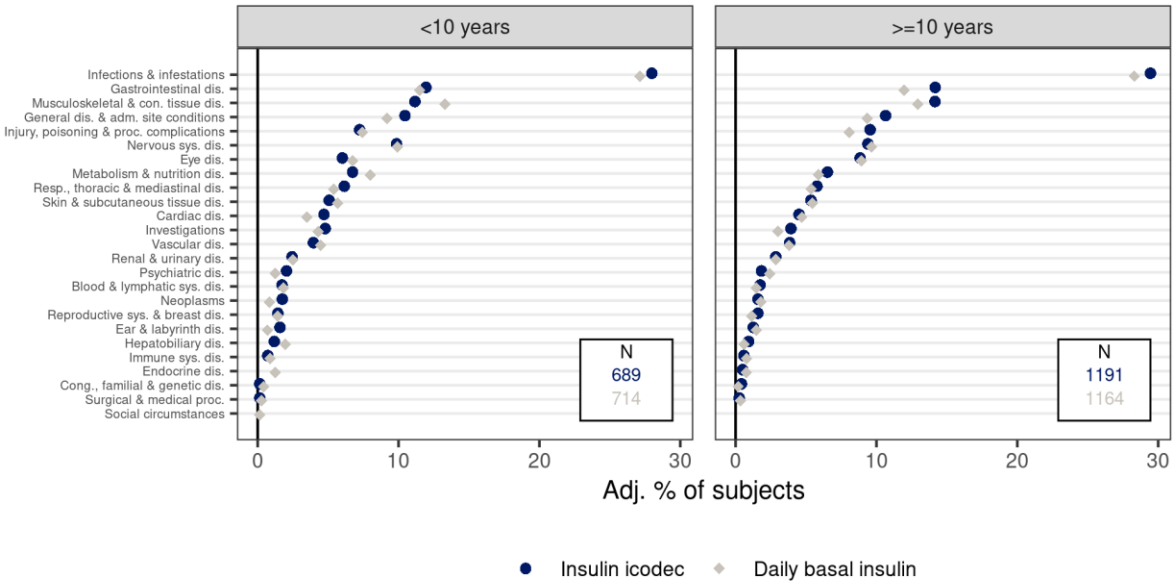



% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): DIABGR1; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS DIABGR1; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:14 - faedotgrp/faesocgrpdiadurdotontp3asas.png

## 7.7.54 Adverse events by diabetes duration and system organ class - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool

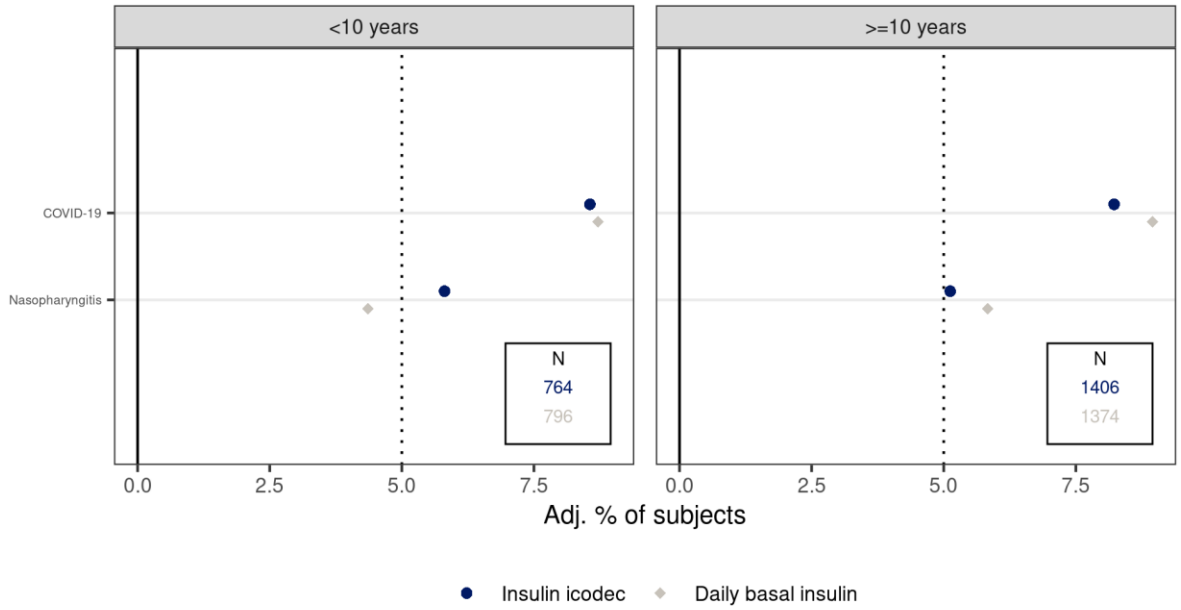



% of subjects: Percentage of subjects with one or more events, N: Number of subjects, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): DIABGR1; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS DIABGR1; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:18 - faedotgrp/faesocgrpdiadurdotontt2dsas.png

## 7.7.55 Adverse events by diabetes duration and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - phase 3a pool

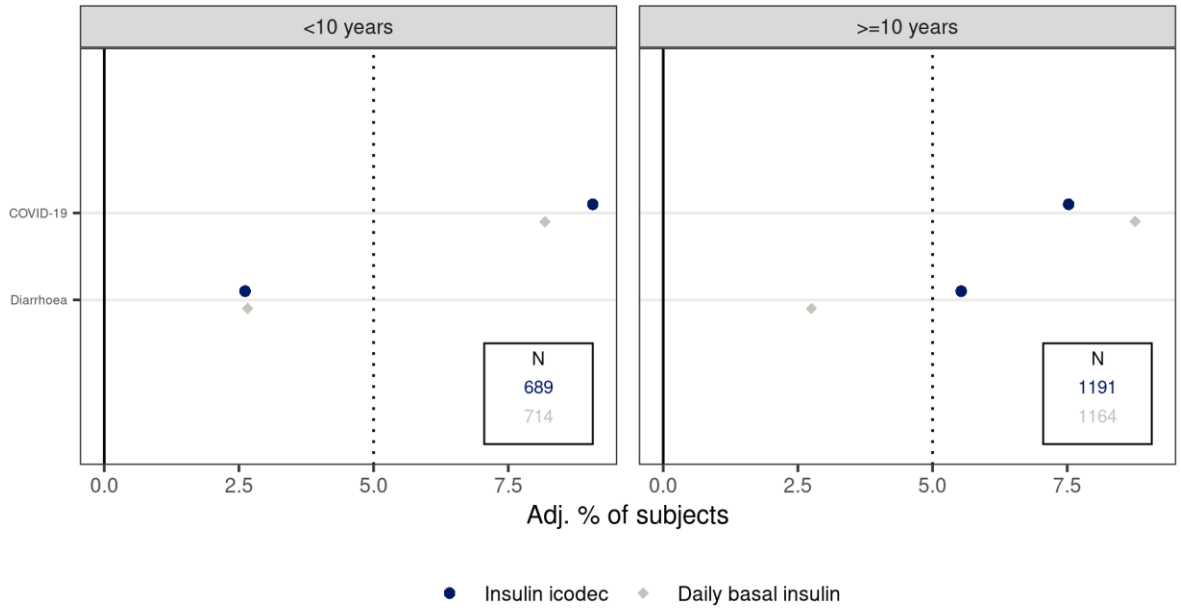



% of subjects: Percentage of subjects with one or more events, N: Number of subjects. Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): DIABGR1; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD DIABGR1; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:22 - faedotgrp/faept5pctgrpdiadurdotontp3asas.png

## 7.7.56 Adverse events by diabetes duration and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - dot plot - safety analysis set - T2D pool




% of subjects: Percentage of subjects with one or more events, N: Number of subjects, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. MedDRA version 24.1. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): DIABGR1; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEDECOD DIABGR1; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:27 - faedotgrp/faept5pctgrpdiadurdotontt2dsas.png

## 7.7.57 Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <25 | 394 | | | | 429 | | | |
| >=25 - <30 | 736 | | | | 747 | | | |
| >=30 - <35 | 600 | | | | 572 | | | |
| >=35 | 440 | | | | 421 | | | |
| Missing | 0 | | | | 1 | | | |
| PYE (years) | | | | | | | | |
| <25 | 277.49 | | | | 292.08 | | | |
| >=25 - <30 | 560.40 | | | | 567.52 | | | |
| >=30 - <35 | 478.51 | | | | 458.12 | | | |
| >=35 | 364.84 | | | | 361.74 | | | |
| Missing | 0.00 | | | | 1.11 | | | |
| Events | | | | | | | | |
| <25 | 233 | (58.8) | 679 | 260.32 | 238 | (55.3) | 756 | 283.79 |
| >=25 - <30 | 452 | (61.4) | 1335 | 253.67 | 452 | (60.6) | 1344 | 252.61 |
| >=30 - <35 | 361 | (60.1) | 1153 | 259.54 | 337 | (59.0) | 1019 | 237.58 |
| >=35 | 282 | (64.0) | 818 | 239.25 | 235 | (55.6) | 758 | 227.82 |
| Missing | 0 | | | | 1 | | 1 | |
| Serious | | | | | | | | |
| Yes | | | | | | | | |
| <25 | 25 | ( 6.2) | 27 | 9.10 | 21 | ( 5.0) | 26 | 9.44 |
| >=25 - <30 | 56 | ( 7.6) | 88 | 15.48 | 58 | ( 7.7) | 81 | 13.31 |
| >=30 - <35 | 49 | ( 8.1) | 73 | 15.99 | 48 | ( 8.3) | 75 | 15.82 |
| >=35 | 36 | ( 8.1) | 57 | 16.76 | 42 | ( 9.8) | 56 | 15.71 |
| Missing | 0 | | | | 0 | | | |
| No | | | | | | | | |
| <25 | 229 | (57.8) | 652 | 251.21 | 233 | (54.2) | 730 | 274.35 |
| >=25 - <30 | 436 | (59.2) | 1247 | 238.19 | 440 | (59.0) | 1263 | 239.31 |
| >=30 - <35 | 347 | (57.7) | 1080 | 243.56 | 325 | (57.0) | 944 | 221.75 |
| >=35 | 275 | (62.4) | 761 | 222.49 | 224 | (53.1) | 702 | 212.11 |
| Missing | 0 | | | | 1 | | 1 | |
| Missing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Severity | | | | | | | | |
| Severe | | | | | | | | |
| <25 | 15 | ( 3.8) | 15 | 5.57 | 14 | ( 3.3) | 15 | 5.21 |
| >=25 - <30 | 33 | ( 4.4) | 41 | 7.35 | 26 | ( 3.5) | 39 | 6.10 |
| >=30 - <35 | 27 | ( 4.5) | 40 | 9.50 | 25 | ( 4.3) | 43 | 9.23 |
| >=35 | 17 | ( 3.8) | 25 | 7.49 | 24 | ( 5.6) | 36 | 8.93 |
| Missing | 0 | | | | 0 | | | |
| Moderate | | | | | | | | |
| <25 | 73 | (18.2) | 136 | 47.39 | 67 | (15.9) | 111 | 40.38 |
| >=25 - <30 | 168 | (22.8) | 288 | 52.51 | 165 | (22.2) | 296 | 53.15 |
| >=30 - <35 | 141 | (23.4) | 267 | 58.93 | 137 | (24.1) | 245 | 55.05 |
| >=35 | 130 | (29.8) | 240 | 69.18 | 109 | (25.9) | 204 | 61.64 |
| Missing | 0 | | | | 0 | | | |
| Mild | | | | | | | | |
| <25 | 202 | (51.0) | 528 | 207.36 | 211 | (48.8) | 630 | 238.20 |
| >=25 - <30 | 381 | (51.8) | 1006 | 193.80 | 397 | (53.2) | 1009 | 193.36 |
| >=30 - <35 | 301 | (50.1) | 846 | 191.11 | 275 | (48.1) | 731 | 173.30 |
| >=35 | 229 | (51.9) | 553 | 162.59 | 189 | (44.9) | 518 | 157.25 |
| Missing | 0 | | | | 1 | | 1 | |
| Missing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Related to basal insulin | | | | | | | | |
| Probable | | | | | | | | |
| <25 | 15 | ( 3.8) | 34 | 13.79 | 14 | ( 3.3) | 26 | 9.49 |
| >=25 - <30 | 37 | ( 5.0) | 51 | 9.96 | 38 | ( 5.0) | 79 | 12.80 |
| >=30 - <35 | 18 | ( 3.0) | 19 | 5.05 | 12 | ( 2.1) | 15 | 3.46 |
| >=35 | 12 | ( 2.8) | 16 | 4.70 | 12 | ( 2.8) | 13 | 3.99 |
| Missing | 0 | | | | 0 | | | |
| Possible | | | | | | | | |
| <25 | 26 | ( 6.7) | 40 | 17.47 | 27 | ( 6.3) | 64 | 24.21 |
| >=25 - <30 | 50 | ( 6.8) | 74 | 14.66 | 36 | ( 4.8) | 47 | 9.34 |
| >=30 - <35 | 28 | ( 4.7) | 37 | 8.94 | 30 | ( 5.3) | 48 | 11.77 |
| >=35 | 21 | ( 4.7) | 28 | 8.89 | 12 | ( 2.9) | 19 | 6.08 |
| Missing | 0 | | | | 0 | | | |
| Unlikely | | | | | | | | |
| <25 | 221 | (55.7) | 601 | 227.36 | 229 | (53.1) | 665 | 249.67 |
| >=25 - <30 | 427 | (58.0) | 1208 | 228.56 | 439 | (58.9) | 1216 | 230.11 |
| >=30 - <35 | 353 | (58.7) | 1095 | 245.12 | 327 | (57.3) | 953 | 221.72 |
| >=35 | 275 | (62.5) | 770 | 224.35 | 230 | (54.4) | 726 | 217.75 |
| Missing | 0 | | | | 1 | | 1 | |
| Missing | | | | | | | | |
| <25 | 2 | ( 0.5) | 4 | 1.69 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 3 | ( 0.5) | 3 | 0.63 |
| >=35 | 2 | ( 0.5) | 4 | 1.31 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Related to technical complaint for basal insulin | | | | | | | | |
| Yes | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 1.20 | 5 | ( 0.7) | 6 | 1.38 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.62 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 4 | ( 0.8) | 4 | 1.41 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| No | | | | | | | | |
| <25 | 233 | (58.8) | 675 | 258.62 | 237 | (55.0) | 754 | 282.97 |
| >=25 - <30 | 451 | (61.2) | 1328 | 251.98 | 451 | (60.5) | 1335 | 250.64 |
| >=30 - <35 | 360 | (59.9) | 1149 | 258.49 | 334 | (58.5) | 1014 | 236.34 |
| >=35 | 281 | (63.8) | 809 | 236.17 | 235 | (55.6) | 758 | 227.82 |
| Missing | 0 | | | | 1 | | 1 | |
| NA | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Missing | | | | | | | | |
| <25 | 2 | ( 0.5) | 4 | 1.69 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 3 | ( 0.4) | 3 | 0.59 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 3 | ( 0.5) | 3 | 0.63 |
| >=35 | 2 | ( 0.5) | 4 | 1.31 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Outcome | | | | | | | | |
| Fatal | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 1.04 | 4 | ( 1.0) | 5 | 1.74 |
| >=25 - <30 | 5 | ( 0.7) | 7 | 1.27 | 3 | ( 0.4) | 3 | 0.39 |
| >=30 - <35 | 4 | ( 0.7) | 6 | 1.65 | 3 | ( 0.5) | 3 | 0.65 |
| >=35 | 2 | ( 0.4) | 2 | 0.59 | 3 | ( 0.7) | 4 | 0.90 |
| Missing | 0 | | | | 0 | | | |
| Not recovered/not resolved | | | | | | | | |
| <25 | 110 | (27.7) | 206 | 76.15 | 114 | (26.4) | 180 | 66.75 |
| >=25 - <30 | 195 | (26.4) | 334 | 61.83 | 191 | (25.5) | 375 | 67.98 |
| >=30 - <35 | 165 | (27.4) | 313 | 68.97 | 150 | (26.3) | 275 | 61.72 |
| >=35 | 119 | (27.0) | 234 | 66.59 | 115 | (27.3) | 212 | 63.68 |
| Missing | 0 | | | | 0 | | | |
| Recovered/resolved with sequelae | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.71 | 2 | ( 0.5) | 2 | 0.67 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.25 | 5 | ( 0.7) | 5 | 1.02 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.90 | 8 | ( 1.4) | 10 | 2.19 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Recovering/resolving | | | | | | | | |
| <25 | 15 | ( 3.7) | 23 | 8.89 | 11 | ( 2.6) | 11 | 3.92 |
| >=25 - <30 | 35 | ( 4.8) | 40 | 8.12 | 33 | ( 4.4) | 40 | 7.81 |
| >=30 - <35 | 22 | ( 3.7) | 45 | 10.84 | 26 | ( 4.5) | 31 | 7.56 |
| >=35 | 24 | ( 5.3) | 28 | 8.52 | 22 | ( 5.3) | 29 | 10.12 |
| Missing | 0 | | | | 0 | | | |
| Recovered/resolved | | | | | | | | |
| <25 | 181 | (45.6) | 443 | 173.29 | 196 | (45.5) | 557 | 210.47 |
| >=25 - <30 | 381 | (51.7) | 952 | 182.19 | 367 | (49.2) | 920 | 175.28 |
| >=30 - <35 | 315 | (52.4) | 785 | 177.19 | 273 | (47.8) | 700 | 165.46 |
| >=35 | 245 | (55.8) | 553 | 163.30 | 202 | (47.7) | 512 | 152.91 |
| Missing | 0 | | | | 1 | | 1 | |
| Unknown | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Missing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

## 7.7.58 Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <25 | 289 | | | | 294 | | | |
| >=25 - <30 | 618 | | | | 645 | | | |
| >=30 - <35 | 554 | | | | 531 | | | |
| >=35 | 419 | | | | 407 | | | |
| Missing | 0 | | | | 1 | | | |
| PYE (years) | | | | | | | | |
| <25 | 226.72 | | | | 224.63 | | | |
| >=25 - <30 | 502.36 | | | | 517.80 | | | |
| >=30 - <35 | 455.36 | | | | 438.19 | | | |
| >=35 | 354.48 | | | | 354.73 | | | |
| Missing | 0.00 | | | | 1.11 | | | |
| Events | | | | | | | | |
| <25 | 177 | (61.0) | 526 | 243.65 | 155 | (52.7) | 411 | 191.32 |
| >=25 - <30 | 369 | (59.8) | 1118 | 232.81 | 380 | (58.9) | 1161 | 232.58 |
| >=30 - <35 | 325 | (58.6) | 1047 | 243.65 | 310 | (58.5) | 948 | 228.08 |
| >=35 | 268 | (63.9) | 787 | 236.79 | 227 | (55.5) | 738 | 225.47 |
| Missing | 0 | | | | 1 | | 1 | |
| Serious | | | | | | | | |
| Yes | | | | | | | | |
| <25 | 21 | ( 7.1) | 23 | 9.60 | 18 | ( 6.1) | 23 | 11.47 |
| >=25 - <30 | 50 | ( 8.1) | 79 | 15.48 | 55 | ( 8.6) | 77 | 14.22 |
| >=30 - <35 | 49 | ( 8.8) | 73 | 17.27 | 47 | ( 8.8) | 73 | 16.29 |
| >=35 | 35 | ( 8.3) | 55 | 16.65 | 42 | (10.2) | 56 | 16.35 |
| Missing | 0 | | | | 0 | | | |
| No | | | | | | | | |
| <25 | 175 | (60.4) | 503 | 234.05 | 152 | (51.8) | 388 | 179.85 |
| >=25 - <30 | 355 | (57.6) | 1039 | 217.34 | 369 | (57.2) | 1084 | 218.37 |
| >=30 - <35 | 311 | (56.1) | 974 | 226.39 | 298 | (56.2) | 875 | 211.80 |
| >=35 | 261 | (62.2) | 732 | 220.14 | 216 | (52.9) | 682 | 209.13 |
| Missing | 0 | | | | 1 | | 1 | |
| Missing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Severity | | | | | | | | |
| Severe | | | | | | | | |
| <25 | 12 | ( 4.1) | 12 | 5.43 | 12 | ( 4.1) | 13 | 6.11 |
| >=25 - <30 | 27 | ( 4.3) | 34 | 6.54 | 25 | ( 3.9) | 38 | 6.81 |
| >=30 - <35 | 27 | ( 4.9) | 40 | 10.26 | 24 | ( 4.5) | 41 | 9.17 |
| >=35 | 17 | ( 3.9) | 25 | 7.80 | 24 | ( 5.8) | 36 | 9.30 |
| Missing | 0 | | | | 0 | | | |
| Moderate | | | | | | | | |
| <25 | 61 | (20.9) | 115 | 49.84 | 48 | (16.6) | 69 | 31.49 |
| >=25 - <30 | 142 | (23.0) | 244 | 48.47 | 143 | (22.3) | 266 | 51.91 |
| >=30 - <35 | 130 | (23.4) | 247 | 56.73 | 131 | (24.8) | 233 | 54.63 |
| >=35 | 128 | (30.7) | 235 | 70.03 | 105 | (25.8) | 199 | 61.24 |
| Missing | 0 | | | | 0 | | | |
| Mild | | | | | | | | |
| <25 | 153 | (52.8) | 399 | 188.39 | 133 | (45.2) | 329 | 153.72 |
| >=25 - <30 | 310 | (50.3) | 840 | 177.81 | 334 | (51.7) | 857 | 173.87 |
| >=30 - <35 | 266 | (48.0) | 760 | 176.66 | 253 | (47.7) | 674 | 164.28 |
| >=35 | 215 | (51.2) | 527 | 158.97 | 182 | (44.7) | 503 | 154.93 |
| Missing | 0 | | | | 1 | | 1 | |
| Missing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Related to basal insulin | | | | | | | | |
| Probable | | | | | | | | |
| <25 | 10 | ( 3.5) | 29 | 15.39 | 9 | ( 3.1) | 20 | 9.73 |
| >=25 - <30 | 27 | ( 4.4) | 38 | 7.80 | 37 | ( 5.7) | 78 | 14.68 |
| >=30 - <35 | 16 | ( 2.9) | 17 | 4.76 | 11 | ( 2.1) | 14 | 3.33 |
| >=35 | 12 | ( 2.9) | 16 | 4.89 | 12 | ( 3.0) | 13 | 4.15 |
| Missing | 0 | | | | 0 | | | |
| Possible | | | | | | | | |
| <25 | 17 | ( 5.9) | 28 | 14.97 | 17 | ( 5.8) | 32 | 14.77 |
| >=25 - <30 | 39 | ( 6.3) | 62 | 13.62 | 32 | ( 4.9) | 43 | 9.57 |
| >=30 - <35 | 27 | ( 4.9) | 36 | 9.31 | 27 | ( 5.1) | 43 | 10.71 |
| >=35 | 20 | ( 4.7) | 27 | 8.86 | 12 | ( 3.0) | 19 | 6.33 |
| Missing | 0 | | | | 0 | | | |
| Unlikely | | | | | | | | |
| <25 | 168 | (57.8) | 465 | 210.91 | 146 | (49.7) | 358 | 166.22 |
| >=25 - <30 | 351 | (56.9) | 1016 | 210.82 | 368 | (57.0) | 1038 | 207.92 |
| >=30 - <35 | 318 | (57.3) | 992 | 229.11 | 300 | (56.6) | 888 | 213.36 |
| >=35 | 261 | (62.3) | 740 | 221.68 | 222 | (54.3) | 706 | 214.99 |
| Missing | 0 | | | | 1 | | 1 | |
| Missing | | | | | | | | |
| <25 | 2 | ( 0.7) | 4 | 2.38 | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 3 | ( 0.6) | 3 | 0.68 |
| >=35 | 2 | ( 0.5) | 4 | 1.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Related to technical complaint for basal insulin | | | | | | | | |
| Yes | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 5 | ( 0.8) | 5 | 1.41 | 5 | ( 0.8) | 6 | 1.62 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.67 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 4 | ( 0.9) | 4 | 1.47 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| No | | | | | | | | |
| <25 | 177 | (61.0) | 522 | 241.27 | 154 | (52.4) | 409 | 190.17 |
| >=25 - <30 | 368 | (59.7) | 1111 | 230.83 | 379 | (58.7) | 1152 | 230.28 |
| >=30 - <35 | 324 | (58.4) | 1043 | 242.51 | 307 | (57.9) | 943 | 226.74 |
| >=35 | 267 | (63.7) | 778 | 233.59 | 227 | (55.5) | 738 | 225.47 |
| Missing | 0 | | | | 1 | | 1 | |
| NA | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Missing | | | | | | | | |
| <25 | 2 | ( 0.7) | 4 | 2.38 | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 3 | ( 0.5) | 3 | 0.69 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 3 | ( 0.6) | 3 | 0.68 |
| >=35 | 2 | ( 0.5) | 4 | 1.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Outcome | | | | | | | | |
| Fatal | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.66 | 4 | ( 1.3) | 5 | 2.45 |
| >=25 - <30 | 5 | ( 0.8) | 7 | 1.49 | 3 | ( 0.5) | 3 | 0.46 |
| >=30 - <35 | 4 | ( 0.7) | 6 | 1.78 | 3 | ( 0.6) | 3 | 0.70 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 3 | ( 0.7) | 4 | 0.94 |
| Missing | 0 | | | | 0 | | | |
| Not recovered/not resolved | | | | | | | | |
| <25 | 87 | (30.1) | 167 | 75.88 | 70 | (24.0) | 104 | 48.11 |
| >=25 - <30 | 158 | (25.6) | 274 | 54.63 | 169 | (26.2) | 332 | 64.77 |
| >=30 - <35 | 147 | (26.5) | 286 | 65.15 | 139 | (26.3) | 256 | 59.03 |
| >=35 | 111 | (26.5) | 226 | 66.15 | 109 | (26.7) | 206 | 62.78 |
| Missing | 0 | | | | 0 | | | |
| Recovered/resolved with sequelae | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.00 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.30 | 4 | ( 0.6) | 4 | 0.84 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.97 | 7 | ( 1.3) | 9 | 1.96 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Recovering/resolving | | | | | | | | |
| <25 | 14 | ( 4.9) | 22 | 11.71 | 10 | ( 3.4) | 10 | 4.91 |
| >=25 - <30 | 32 | ( 5.2) | 37 | 8.63 | 31 | ( 4.8) | 37 | 8.12 |
| >=30 - <35 | 20 | ( 3.6) | 43 | 11.02 | 25 | ( 4.7) | 30 | 7.76 |
| >=35 | 24 | ( 5.5) | 28 | 8.87 | 21 | ( 5.2) | 26 | 8.78 |
| Missing | 0 | | | | 0 | | | |
| Recovered/resolved | | | | | | | | |
| <25 | 136 | (46.8) | 331 | 154.08 | 126 | (43.0) | 290 | 135.19 |
| >=25 - <30 | 308 | (49.9) | 798 | 167.76 | 307 | (47.6) | 784 | 158.24 |
| >=30 - <35 | 282 | (50.9) | 708 | 164.74 | 249 | (47.0) | 650 | 158.63 |
| >=35 | 236 | (56.3) | 530 | 160.89 | 195 | (47.6) | 501 | 152.75 |
| Missing | 0 | | | | 1 | | 1 | |
| Unknown | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Missing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

## 7.7.59 Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on- treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <25 | 394 | | | | 429 | | | |
| >=25 - <30 | 736 | | | | 747 | | | |
| >=30 - <35 | 600 | | | | 572 | | | |
| >=35 | 440 | | | | 421 | | | |
| Missing | 0 | | | | 1 | | | |
| PYE (years) | | | | | | | | |
| <25 | 277.49 | | | | 292.08 | | | |
| >=25 - <30 | 560.40 | | | | 567.52 | | | |
| >=30 - <35 | 478.51 | | | | 458.12 | | | |
| >=35 | 364.84 | | | | 361.74 | | | |
| Missing | 0.00 | | | | 1.11 | | | |
| Events | | | | | | | | |
| <25 | 233 | (58.8) | 679 | 260.32 | 238 | (55.3) | 756 | 283.79 |
| >=25 - <30 | 452 | (61.4) | 1335 | 253.67 | 452 | (60.6) | 1344 | 252.61 |
| >=30 - <35 | 361 | (60.1) | 1153 | 259.54 | 337 | (59.0) | 1019 | 237.58 |
| >=35 | 282 | (64.0) | 818 | 239.25 | 235 | (55.6) | 758 | 227.82 |
| Missing | 0 | | | | 1 | | 1 | |
| Infections and infestations | | | | | | | | |
| All | | | | | | | | |
| <25 | 99 | (25.0) | 139 | 54.01 | 103 | (23.9) | 136 | 49.87 |
| >=25 - <30 | 216 | (29.2) | 299 | 58.81 | 211 | (28.4) | 309 | 60.70 |
| >=30 - <35 | 188 | (31.3) | 268 | 63.12 | 171 | (30.0) | 247 | 57.78 |
| >=35 | 145 | (32.9) | 214 | 62.95 | 139 | (32.8) | 213 | 62.34 |
| Missing | 0 | | | | 0 | | | |
| COVID-19 | | | | | | | | |
| <25 | 23 | ( 5.8) | 24 | 9.07 | 33 | ( 7.7) | 35 | 12.35 |
| >=25 - <30 | 57 | ( 7.7) | 59 | 11.36 | 64 | ( 8.7) | 65 | 11.73 |
| >=30 - <35 | 51 | ( 8.5) | 51 | 11.89 | 40 | ( 7.0) | 40 | 9.41 |
| >=35 | 50 | (11.4) | 51 | 14.87 | 55 | (12.9) | 59 | 16.96 |
| Missing | 0 | | | | 0 | | | |
| Nasopharyngitis | | | | | | | | |
| <25 | 29 | ( 7.4) | 35 | 14.44 | 26 | ( 5.9) | 30 | 11.71 |
| >=25 - <30 | 40 | ( 5.3) | 47 | 9.51 | 44 | ( 6.0) | 53 | 11.55 |
| >=30 - <35 | 34 | ( 5.6) | 41 | 10.69 | 28 | ( 4.9) | 32 | 8.35 |
| >=35 | 14 | ( 3.2) | 18 | 5.71 | 17 | ( 4.1) | 20 | 6.57 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Upper respiratory tract infection | | | | | | | | |
| <25 | 12 | ( 3.0) | 12 | 4.67 | 5 | ( 1.2) | 5 | 1.59 |
| >=25 - <30 | 20 | ( 2.7) | 25 | 4.37 | 19 | ( 2.5) | 22 | 4.42 |
| >=30 - <35 | 19 | ( 3.2) | 23 | 4.78 | 14 | ( 2.5) | 14 | 3.38 |
| >=35 | 17 | ( 4.0) | 21 | 6.04 | 14 | ( 3.3) | 15 | 4.31 |
| Missing | 0 | | | | 0 | | | |
| Influenza | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 5 | ( 1.2) | 5 | 1.89 |
| >=25 - <30 | 13 | ( 1.8) | 14 | 3.06 | 15 | ( 2.0) | 17 | 3.99 |
| >=30 - <35 | 9 | ( 1.5) | 10 | 2.84 | 10 | ( 1.8) | 11 | 2.76 |
| >=35 | 6 | ( 1.3) | 7 | 2.21 | 3 | ( 0.8) | 3 | 1.35 |
| Missing | 0 | | | | 0 | | | |
| Urinary tract infection | | | | | | | | |
| <25 | 9 | ( 2.3) | 9 | 3.55 | 3 | ( 0.7) | 3 | 0.93 |
| >=25 - <30 | 13 | ( 1.8) | 14 | 2.86 | 19 | ( 2.6) | 23 | 4.27 |
| >=30 - <35 | 13 | ( 2.2) | 15 | 3.48 | 18 | ( 3.2) | 20 | 4.59 |
| >=35 | 8 | ( 1.8) | 8 | 2.33 | 10 | ( 2.3) | 10 | 3.00 |
| Missing | 0 | | | | 0 | | | |
| Bronchitis | | | | | | | | |
| <25 | 5 | ( 1.3) | 5 | 2.36 | 4 | ( 0.9) | 4 | 1.32 |
| >=25 - <30 | 13 | ( 1.8) | 13 | 2.51 | 5 | ( 0.7) | 5 | 1.03 |
| >=30 - <35 | 6 | ( 1.0) | 6 | 1.58 | 6 | ( 1.1) | 6 | 1.37 |
| >=35 | 6 | ( 1.4) | 7 | 1.80 | 4 | ( 1.0) | 4 | 1.12 |
| Missing | 0 | | | | 0 | | | |
| Gastroenteritis | | | | | | | | |
| <25 | 3 | ( 0.8) | 4 | 2.16 | 3 | ( 0.7) | 3 | 1.12 |
| >=25 - <30 | 10 | ( 1.4) | 10 | 2.20 | 8 | ( 1.1) | 9 | 1.87 |
| >=30 - <35 | 10 | ( 1.7) | 10 | 2.65 | 4 | ( 0.7) | 4 | 0.94 |
| >=35 | 9 | ( 2.0) | 9 | 2.74 | 3 | ( 0.7) | 3 | 1.09 |
| Missing | 0 | | | | 0 | | | |
| Pharyngitis | | | | | | | | |
| <25 | 4 | ( 1.0) | 4 | 1.84 | 1 | ( 0.2) | 2 | 0.79 |
| >=25 - <30 | 8 | ( 1.1) | 8 | 1.55 | 8 | ( 1.1) | 8 | 1.53 |
| >=30 - <35 | 7 | ( 1.2) | 8 | 1.60 | 5 | ( 0.9) | 6 | 1.31 |
| >=35 | 2 | ( 0.5) | 3 | 0.78 | 4 | ( 0.9) | 5 | 1.33 |
| Missing | 0 | | | | 0 | | | |
| Sinusitis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 6 | ( 0.8) | 8 | 1.63 | 6 | ( 0.8) | 6 | 1.38 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 1.29 | 7 | ( 1.2) | 8 | 1.90 |
| >=35 | 7 | ( 1.6) | 7 | 2.03 | 5 | ( 1.1) | 7 | 1.55 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Pneumonia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.92 | 0 | | | |
| >=25 - <30 | 5 | ( 0.7) | 5 | 1.01 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 1.08 | 4 | ( 0.7) | 4 | 0.93 |
| >=35 | 3 | ( 0.7) | 3 | 0.87 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Tooth infection | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 5 | ( 0.7) | 6 | 1.11 | 2 | ( 0.3) | 2 | 0.46 |
| >=30 - <35 | 2 | ( 0.3) | 3 | 0.71 | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 3 | ( 0.7) | 3 | 1.09 |
| Missing | 0 | | | | 0 | | | |
| COVID-19 pneumonia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.98 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 0.93 | 7 | ( 1.2) | 7 | 1.47 |
| >=35 | 5 | ( 1.1) | 5 | 1.54 | 2 | ( 0.5) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Conjunctivitis | | | | | | | | |
| <25 | 4 | ( 1.1) | 4 | 1.94 | 3 | ( 0.7) | 3 | 1.05 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.78 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 2 | ( 0.4) | 2 | 0.59 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vaginal infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 4 | ( 0.5) | 5 | 1.12 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Rhinitis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.4) | 2 | 0.86 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.78 | 6 | ( 0.8) | 9 | 2.03 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.65 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.5) | 2 | 0.66 |
| Missing | 0 | | | | 0 | | | |
| Cystitis | | | | | | | | |
| <25 | 4 | ( 0.9) | 5 | 1.18 | 4 | ( 1.0) | 4 | 1.22 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.89 | 6 | ( 0.8) | 7 | 1.39 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 1.39 | 4 | ( 0.7) | 5 | 1.14 |
| >=35 | 2 | ( 0.4) | 2 | 0.69 | 3 | ( 0.7) | 3 | 0.66 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Fungal infection | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.63 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 2 | ( 0.3) | 2 | 0.47 |
| >=35 | 2 | ( 0.5) | 3 | 0.98 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Otitis media | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.51 | 3 | ( 0.4) | 3 | 0.66 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.56 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Tonsillitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.51 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastroenteritis viral | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.51 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 2 | ( 0.4) | 2 | 0.64 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Herpes zoster | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 6 | ( 1.4) | 6 | 2.04 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.63 | 6 | ( 0.8) | 7 | 1.09 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.80 | 3 | ( 0.5) | 3 | 0.63 |
| >=35 | 3 | ( 0.7) | 3 | 0.75 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Respiratory tract infection viral | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.27 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.74 | 4 | ( 0.5) | 4 | 0.89 |
| >=30 - <35 | 3 | ( 0.5) | 4 | 0.95 | 3 | ( 0.5) | 3 | 0.76 |
| >=35 | 3 | ( 0.6) | 3 | 1.08 | 2 | ( 0.5) | 3 | 1.38 |
| Missing | 0 | | | | 0 | | | |
| Tooth abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.46 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 4 | ( 0.6) | 4 | 1.08 | 5 | ( 0.9) | 5 | 1.00 |
| >=35 | 3 | ( 0.7) | 3 | 0.87 | 1 | ( 0.3) | 2 | 0.92 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Coronavirus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 2 | ( 0.4) | 3 | 0.55 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.5) | 3 | 1.14 |
| Missing | 0 | | | | 0 | | | |
| Erysipelas | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 1 | ( 0.3) | 2 | 0.88 |
| Missing | 0 | | | | 0 | | | |
| Vulvitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.50 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gingivitis | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.82 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 2 | 0.52 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Viral infection | | | | | | | | |
| <25 | 0 | | | | 4 | ( 0.9) | 4 | 1.71 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 3 | ( 0.4) | 3 | 0.49 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.64 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 2 | ( 0.4) | 2 | 0.58 | 4 | ( 0.9) | 7 | 1.57 |
| Missing | 0 | | | | 0 | | | |
| Anal abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cellulitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 3 | ( 0.5) | 3 | 0.64 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 3 | ( 0.7) | 4 | 1.53 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Ear infection | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 3 | ( 0.5) | 3 | 0.65 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Tinea versicolour | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Varicella zoster virus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acute sinusitis | | | | | | | | |
| <25 | 0 | | | | 3 | ( 0.7) | 3 | 1.25 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.49 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Genital candidiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Otitis externa | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.86 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 2 | ( 0.5) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Sepsis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Bacterial infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Candida infection | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Escherichia urinary tract infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Furuncle | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.28 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Herpes virus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Laryngopharyngitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Localised infection | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lower respiratory tract infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.65 | 1 | ( 0.2) | 3 | 0.55 |
| >=35 | 2 | ( 0.5) | 2 | 0.52 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Onychomycosis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Respiratory syncytial virus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tracheitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urethritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vulvovaginal mycotic infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bacteraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Respiratory tract infection | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.81 | 2 | ( 0.5) | 2 | 0.65 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 6 | ( 1.4) | 6 | 1.70 | 3 | ( 0.6) | 3 | 0.65 |
| Missing | 0 | | | | 0 | | | |
| Acarodermatitis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Clostridium difficile infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Genital infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Laryngitis | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.82 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Abscess limb | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 2 | 0.74 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Fungal skin infection | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 3 | ( 0.5) | 4 | 1.30 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Periodontitis | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.94 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 3 | ( 0.4) | 3 | 0.66 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Severe acute respiratory syndrome | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tinea cruris | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vulvovaginitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Abdominal abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Appendicitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asymptomatic COVID-19 | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Balanitis candida | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Bartholinitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Body tinea | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breast abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Breast cellulitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Campylobacter gastroenteritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chlamydial infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cholecystitis infective | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic hepatitis C | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic sinusitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Chronic tonsillitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Clostridium difficile colitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cystitis escherichia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dermatophytosis of nail | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic foot infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diverticulitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Ear infection fungal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Empyema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Endophthalmitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Enteritis infectious | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epididymitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Escherichia bacteraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.47 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye infection bacterial | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Folliculitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Fungal balanitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gangrene | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastroenteritis norovirus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Genital infection fungal | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.4) | 3 | 1.02 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Giardiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Helicobacter gastritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Helicobacter infection | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Herpes dermatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Herpes simplex | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Herpes zoster infection neurological | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hordeolum | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 2 | ( 0.5) | 2 | 0.66 |
| Missing | 0 | | | | 0 | | | |
| Infected bite | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Infected cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Infected dermal cyst | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Infective iritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Kidney infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Labyrinthitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lyme disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mastitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nail infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 2 | 0.46 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Norovirus infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oophoritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Oral candidiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral herpes | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 3 | 0.90 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oropharyngeal candidiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteomyelitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Otitis media acute | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 3 | ( 0.5) | 3 | 0.64 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Otitis media chronic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Paraspinal abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Paronychia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.47 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Parotitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Peri-implantitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pericoronitis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peritonsillar abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Pharyngotonsillitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Pneumonia viral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural infection | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post-acute COVID-19 syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 2 | 0.46 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Postoperative wound infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary tuberculoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulpitis dental | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Purulence | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pustule | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pyelonephritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rotavirus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Salpingitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Sinusitis bacterial | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin bacterial infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Skin candida | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Skin infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Soft tissue infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Subcutaneous abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.27 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Suspected COVID-19 | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sweat gland infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Tinea infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Tinea pedis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 2 | ( 0.4) | 2 | 0.73 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urosepsis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Varicella | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral pharyngitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral rhinitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral tracheitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral upper respiratory tract infection | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vulvovaginal candidiasis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 2 | 0.52 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Wound infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.59 | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 43 | (10.7) | 68 | 23.77 | 43 | (10.1) | 59 | 22.03 |
| >=25 - <30 | 98 | (13.4) | 135 | 25.14 | 93 | (12.3) | 129 | 23.42 |
| >=30 - <35 | 83 | (13.7) | 141 | 31.67 | 60 | (10.5) | 84 | 20.09 |
| >=35 | 53 | (12.2) | 74 | 20.65 | 49 | (11.6) | 71 | 21.55 |
| Missing | 0 | | | | 0 | | | |
| Diarrhoea | | | | | | | | |
| <25 | 13 | ( 3.2) | 18 | 6.40 | 4 | ( 0.9) | 4 | 1.52 |
| >=25 - <30 | 24 | ( 3.3) | 26 | 4.53 | 24 | ( 3.2) | 24 | 4.55 |
| >=30 - <35 | 30 | ( 4.9) | 40 | 8.84 | 13 | ( 2.3) | 14 | 3.08 |
| >=35 | 22 | ( 5.0) | 24 | 7.13 | 14 | ( 3.4) | 15 | 5.40 |
| Missing | 0 | | | | 0 | | | |
| Nausea | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.66 | 6 | ( 1.3) | 6 | 2.54 |
| >=25 - <30 | 18 | ( 2.5) | 18 | 3.03 | 9 | ( 1.2) | 9 | 1.77 |
| >=30 - <35 | 15 | ( 2.5) | 16 | 3.61 | 10 | ( 1.7) | 12 | 2.82 |
| >=35 | 6 | ( 1.3) | 6 | 1.95 | 10 | ( 2.4) | 10 | 3.20 |
| Missing | 0 | | | | 0 | | | |
| Vomiting | | | | | | | | |
| <25 | 4 | ( 1.0) | 5 | 2.17 | 4 | ( 0.9) | 4 | 1.71 |
| >=25 - <30 | 14 | ( 1.9) | 17 | 3.80 | 7 | ( 0.9) | 8 | 1.31 |
| >=30 - <35 | 8 | ( 1.3) | 12 | 2.67 | 4 | ( 0.7) | 4 | 1.26 |
| >=35 | 5 | ( 1.0) | 5 | 1.69 | 6 | ( 1.3) | 8 | 1.96 |
| Missing | 0 | | | | 0 | | | |
| Gastrooesophageal reflux disease | | | | | | | | |
| <25 | 4 | ( 1.0) | 4 | 1.49 | 2 | ( 0.5) | 2 | 0.69 |
| >=25 - <30 | 6 | ( 0.8) | 6 | 1.02 | 6 | ( 0.8) | 6 | 1.15 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.64 | 5 | ( 0.9) | 5 | 1.14 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Constipation | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 3 | ( 0.7) | 3 | 0.89 | 4 | ( 0.9) | 4 | 1.45 |
| >=25 - <30 | 5 | ( 0.7) | 6 | 1.24 | 5 | ( 0.6) | 5 | 0.93 |
| >=30 - <35 | 5 | ( 0.8) | 7 | 1.78 | 5 | ( 0.9) | 5 | 1.12 |
| >=35 | 4 | ( 0.9) | 4 | 1.08 | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Abdominal pain | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.92 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 1.10 | 3 | ( 0.4) | 3 | 0.69 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 1.08 | 9 | ( 1.6) | 10 | 2.36 |
| >=35 | 4 | ( 1.0) | 4 | 0.98 | 5 | ( 1.2) | 5 | 1.35 |
| Missing | 0 | | | | 0 | | | |
| Toothache | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.23 | 5 | ( 1.1) | 7 | 2.86 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.90 | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.66 | 3 | ( 0.5) | 4 | 1.34 |
| >=35 | 3 | ( 0.7) | 3 | 0.75 | 3 | ( 0.7) | 5 | 1.94 |
| Missing | 0 | | | | 0 | | | |
| Abdominal pain upper | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.80 | 3 | ( 0.8) | 3 | 0.72 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.75 | 6 | ( 0.8) | 6 | 1.04 |
| >=30 - <35 | 6 | ( 1.0) | 8 | 2.22 | 4 | ( 0.7) | 4 | 1.06 |
| >=35 | 3 | ( 0.7) | 3 | 0.72 | 3 | ( 0.7) | 4 | 1.12 |
| Missing | 0 | | | | 0 | | | |
| Abdominal distension | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.65 | 3 | ( 0.4) | 3 | 0.60 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.65 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Abdominal discomfort | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 3 | 1.04 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.77 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| Missing | 0 | | | | 0 | | | |
| Food poisoning | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.51 | 3 | ( 0.4) | 4 | 0.79 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Chronic gastritis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.53 | 3 | ( 0.4) | 3 | 0.56 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 1.06 | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gastritis | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.80 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 5 | ( 0.7) | 5 | 0.65 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.45 | 3 | ( 0.5) | 3 | 0.92 |
| >=35 | 2 | ( 0.4) | 2 | 0.58 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Abdominal pain lower | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dental caries | | | | | | | | |
| <25 | 5 | ( 1.2) | 6 | 1.74 | 2 | ( 0.5) | 2 | 0.82 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 5 | ( 0.7) | 5 | 0.95 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.50 | 0 | | | |
| >=35 | 2 | ( 0.5) | 3 | 0.75 | 3 | ( 0.7) | 3 | 0.90 |
| Missing | 0 | | | | 0 | | | |
| Hypoaesthesia oral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 4 | 0.93 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dry mouth | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Flatulence | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 2 | ( 0.3) | 2 | 0.44 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hiatus hernia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperaesthesia teeth | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intra-abdominal haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Dyspepsia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 5 | ( 0.7) | 5 | 1.00 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.88 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 2 | ( 0.5) | 2 | 0.59 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Gastric polyps | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 3 | ( 0.4) | 3 | 0.65 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemorrhoids | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.60 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 2 | ( 0.5) | 2 | 0.46 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Noninfective gingivitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haematochezia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Loose tooth | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tooth impacted | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Proctalgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Abdominal wall disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aphthous ulcer | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eructation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric ulcer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lip swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Umbilical hernia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anal fissure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Acid peptic disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anal pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colitis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Colitis ischaemic | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colitis microscopic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Crohn's disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic gastropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diverticulum | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diverticulum intestinal | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.48 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Duodenitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Enteritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Enterocolitis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 3 | 0.49 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eosinophilic oesophagitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epigastric discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Faeces pale | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Faeces soft | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Frequent bowel movements | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric dilatation | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric dysplasia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric mucosal hypertrophy | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastritis erosive | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal angiodysplasia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal sounds abnormal | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gingival bleeding | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gingival disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gingival recession | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 2 | 0.86 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemorrhoidal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperchlorhydria | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ileus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Impaired gastric emptying | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 3 | 0.81 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inguinal hernia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intestinal dilatation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Irritable bowel syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 1 | ( 0.2) | 1 | 0.18 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Large intestine polyp | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 4 | ( 0.5) | 5 | 0.75 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 2 | ( 0.3) | 2 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lumbar hernia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Melaena | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Mesenteric panniculitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Odynophagia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oesophageal pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Oesophagitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic duct dilatation | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic failure | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic pseudocyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Pancreatitis acute | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatitis chronic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peptic ulcer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Periodontal disease | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.82 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Periodontal inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.36 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pneumatosis intestinalis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rectal polyp | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rectal prolapse | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Small intestinal obstruction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Stomatitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tongue rough | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Tooth disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ulcerative gastritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Upper gastrointestinal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vomiting projectile | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 40 | (10.1) | 52 | 21.31 | 50 | (11.6) | 79 | 30.17 |
| >=25 - <30 | 84 | (11.5) | 122 | 21.87 | 90 | (12.1) | 117 | 21.83 |
| >=30 - <35 | 91 | (15.1) | 139 | 29.48 | 77 | (13.6) | 107 | 24.58 |
| >=35 | 58 | (13.3) | 87 | 25.05 | 67 | (15.9) | 98 | 30.78 |
| Missing | 0 | | | | 0 | | | |
| Back pain | | | | | | | | |
| <25 | 10 | ( 2.5) | 11 | 4.16 | 12 | ( 2.8) | 27 | 10.67 |
| >=25 - <30 | 23 | ( 3.2) | 25 | 4.53 | 22 | ( 3.0) | 22 | 4.46 |
| >=30 - <35 | 19 | ( 3.1) | 19 | 4.10 | 18 | ( 3.2) | 19 | 4.86 |
| >=35 | 13 | ( 3.0) | 14 | 3.83 | 20 | ( 4.7) | 21 | 6.86 |
| Missing | 0 | | | | 0 | | | |
| Arthralgia | | | | | | | | |
| <25 | 5 | ( 1.2) | 5 | 1.70 | 11 | ( 2.6) | 11 | 4.12 |
| >=25 - <30 | 17 | ( 2.3) | 21 | 3.97 | 13 | ( 1.8) | 14 | 2.87 |
| >=30 - <35 | 20 | ( 3.3) | 22 | 4.52 | 18 | ( 3.2) | 21 | 4.95 |
| >=35 | 9 | ( 2.0) | 11 | 3.49 | 15 | ( 3.6) | 17 | 5.62 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Pain in extremity | | | | | | | | |
| <25 | 4 | ( 1.0) | 4 | 1.82 | 7 | ( 1.6) | 8 | 3.22 |
| >=25 - <30 | 9 | ( 1.2) | 9 | 1.33 | 16 | ( 2.1) | 20 | 4.08 |
| >=30 - <35 | 14 | ( 2.3) | 15 | 3.16 | 6 | ( 1.1) | 6 | 1.34 |
| >=35 | 10 | ( 2.3) | 11 | 3.16 | 8 | ( 1.8) | 9 | 2.43 |
| Missing | 0 | | | | 0 | | | |
| Osteoarthritis | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 1.04 | 3 | ( 0.7) | 3 | 1.10 |
| >=25 - <30 | 7 | ( 0.9) | 8 | 1.42 | 8 | ( 1.1) | 10 | 1.61 |
| >=30 - <35 | 6 | ( 1.0) | 7 | 1.45 | 10 | ( 1.8) | 11 | 2.41 |
| >=35 | 8 | ( 1.8) | 8 | 2.41 | 5 | ( 1.2) | 5 | 1.82 |
| Missing | 0 | | | | 0 | | | |
| Myalgia | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.56 | 9 | ( 2.0) | 9 | 3.75 |
| >=25 - <30 | 6 | ( 0.8) | 6 | 1.13 | 4 | ( 0.6) | 5 | 1.15 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 1.06 | 2 | ( 0.4) | 2 | 0.55 |
| >=35 | 3 | ( 0.7) | 3 | 0.82 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Trigger finger | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 5 | ( 0.7) | 5 | 1.22 | 2 | ( 0.3) | 4 | 0.53 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.54 |
| >=35 | 3 | ( 0.7) | 3 | 0.85 | 2 | ( 0.5) | 2 | 0.66 |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc protrusion | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 4 | ( 0.6) | 5 | 0.70 | 2 | ( 0.3) | 2 | 0.44 |
| >=30 - <35 | 1 | ( 0.2) | 4 | 0.67 | 2 | ( 0.4) | 3 | 0.55 |
| >=35 | 2 | ( 0.5) | 2 | 0.59 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Muscle spasms | | | | | | | | |
| <25 | 5 | ( 1.3) | 7 | 3.11 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.52 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 11 | ( 1.8) | 11 | 2.49 | 4 | ( 0.7) | 4 | 0.82 |
| >=35 | 6 | ( 1.4) | 6 | 1.86 | 2 | ( 0.5) | 2 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Osteoporosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscular weakness | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 2 | ( 0.3) | 2 | 0.44 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Neck pain | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.27 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 9 | ( 1.5) | 9 | 2.14 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 2 | ( 0.5) | 2 | 0.59 | 4 | ( 0.9) | 4 | 1.11 |
| Missing | 0 | | | | 0 | | | |
| Periarthritis | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.66 | 6 | ( 1.4) | 6 | 2.04 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.64 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Plantar fasciitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal osteoarthritis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Tendonitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 5 | ( 0.8) | 7 | 1.60 | 3 | ( 0.5) | 3 | 0.78 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arthritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.50 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 4 | ( 0.9) | 4 | 1.05 | 2 | ( 0.5) | 2 | 0.89 |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal stiffness | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.50 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Axillary mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Flank pain | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.53 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 3 | 0.63 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Polymyalgia rheumatica | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 3 | 1.29 |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pain in jaw | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tendon disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Back disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Coccydynia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lumbar spinal stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal chest pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Myositis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Osteopenia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Spinal stenosis | | | | | | | | |
| <25 | 1 | ( 0.2) | 2 | 0.85 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.55 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Synovial cyst | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acquired claw toe | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bursitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.22 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Diastasis recti abdominis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Foot deformity | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 2 | ( 0.4) | 3 | 0.82 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Polyarthritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sacroiliitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Limb discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arthropathy | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Cervical spinal stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chondromalacia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chondropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Costochondritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Dupuytren's contracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Exostosis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.46 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Facet joint syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fibromyalgia | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fistula | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Groin pain | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemarthrosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.60 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc space narrowing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Jaw disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Joint effusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 2 | ( 0.4) | 3 | 0.92 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Joint swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 3 | ( 0.5) | 3 | 0.80 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Limb deformity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Limb mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mastication disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Meniscopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle contracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle twitching | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Neuropathic arthropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nodal osteoarthritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.54 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteochondritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteochondrosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 3 | ( 0.8) | 3 | 1.15 |
| Missing | 0 | | | | 0 | | | |
| Periostitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Psoriatic arthropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rheumatoid arthritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 3 | ( 0.4) | 3 | 0.64 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rotator cuff syndrome | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 4 | ( 0.6) | 4 | 0.52 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.60 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scoliosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Soft tissue swelling | | | | | | | | |
| <25 | 1 | ( 0.2) | 3 | 1.27 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.87 |
| Missing | 0 | | | | 0 | | | |
| Spinal retrolisthesis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Tenosynovitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 4 | ( 0.5) | 4 | 0.53 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.4) | 3 | 0.67 |
| >=35 | 0 | | | | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Tenosynovitis stenosans | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Torticollis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vertebral osteophyte | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| General disorders and administration site conditions | | | | | | | | |
| All | | | | | | | | |
| <25 | 48 | (12.1) | 80 | 31.21 | 49 | (11.5) | 107 | 40.39 |
| >=25 - <30 | 70 | ( 9.5) | 120 | 24.55 | 62 | ( 8.4) | 108 | 20.08 |
| >=30 - <35 | 71 | (11.8) | 99 | 23.48 | 58 | (10.2) | 82 | 18.43 |
| >=35 | 51 | (11.6) | 64 | 18.92 | 39 | ( 9.1) | 47 | 13.67 |
| Missing | 0 | | | | 0 | | | |
| Pyrexia | | | | | | | | |
| <25 | 12 | ( 3.0) | 12 | 4.10 | 13 | ( 3.1) | 13 | 4.34 |
| >=25 - <30 | 14 | ( 1.9) | 16 | 3.34 | 16 | ( 2.1) | 17 | 3.13 |
| >=30 - <35 | 11 | ( 1.8) | 11 | 2.46 | 8 | ( 1.4) | 9 | 2.11 |
| >=35 | 4 | ( 0.9) | 4 | 1.20 | 6 | ( 1.5) | 6 | 2.19 |
| Missing | 0 | | | | 0 | | | |
| Fatigue | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.93 | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 8 | ( 1.1) | 9 | 1.69 | 3 | ( 0.4) | 3 | 0.64 |
| >=30 - <35 | 10 | ( 1.7) | 12 | 2.86 | 6 | ( 1.0) | 6 | 1.27 |
| >=35 | 11 | ( 2.5) | 12 | 3.64 | 6 | ( 1.3) | 6 | 1.52 |
| Missing | 0 | | | | 0 | | | |
| Hunger | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 7 | ( 1.0) | 8 | 1.33 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.74 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site pain | | | | | | | | |
| <25 | 3 | ( 0.7) | 4 | 1.54 | 3 | ( 0.7) | 3 | 1.28 |
| >=25 - <30 | 6 | ( 0.8) | 7 | 1.26 | 2 | ( 0.3) | 2 | 0.45 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 3 | ( 0.5) | 3 | 0.65 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Oedema peripheral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 5 | ( 0.7) | 5 | 1.11 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 8 | ( 1.3) | 8 | 1.69 | 5 | ( 0.9) | 6 | 1.18 |
| >=35 | 6 | ( 1.3) | 6 | 1.74 | 3 | ( 0.7) | 3 | 0.90 |
| Missing | 0 | | | | 0 | | | |
| Malaise | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 5 | ( 1.3) | 5 | 2.03 | 3 | ( 0.7) | 40 | 16.80 |
| >=25 - <30 | 5 | ( 0.7) | 6 | 0.92 | 8 | ( 1.1) | 14 | 2.97 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.63 | 4 | ( 0.7) | 6 | 1.47 |
| >=35 | 4 | ( 0.9) | 5 | 1.28 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site reaction | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.92 | 1 | ( 0.3) | 3 | 0.72 |
| >=25 - <30 | 4 | ( 0.6) | 14 | 3.30 | 3 | ( 0.4) | 3 | 0.48 |
| >=30 - <35 | 6 | ( 1.0) | 10 | 2.84 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 3 | ( 0.7) | 3 | 0.92 | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Asthenia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.70 | 2 | ( 0.5) | 2 | 0.69 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.66 | 3 | ( 0.4) | 3 | 0.75 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 4 | ( 0.7) | 4 | 0.83 |
| >=35 | 3 | ( 0.7) | 3 | 0.94 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Chest pain | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.89 | 0 | | | |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.75 | 4 | ( 0.5) | 4 | 0.69 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 0.97 | 2 | ( 0.3) | 2 | 0.33 |
| >=35 | 2 | ( 0.4) | 2 | 0.59 | 1 | ( 0.3) | 1 | 0.56 |
| Missing | 0 | | | | 0 | | | |
| Medical device site bruise | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 4 | 0.88 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 2 | 0.52 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.75 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.63 | 0 | | | |
| >=35 | 2 | ( 0.5) | 4 | 1.14 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Injection site swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chest discomfort | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.49 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 2 | ( 0.4) | 2 | 0.72 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Injection site erythema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 4 | 0.97 | 3 | ( 0.4) | 3 | 0.40 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Gait disturbance | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site pruritus | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.86 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.50 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.49 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pain | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.69 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 6 | ( 1.0) | 7 | 2.01 | 7 | ( 1.2) | 7 | 1.59 |
| >=35 | 3 | ( 0.7) | 3 | 0.98 | 4 | ( 0.9) | 5 | 1.53 |
| Missing | 0 | | | | 0 | | | |
| Swelling face | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Influenza like illness | | | | | | | | |
| <25 | 2 | ( 0.5) | 3 | 1.03 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.51 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.84 | 1 | ( 0.2) | 1 | 0.16 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Medical device site rash | | | | | | | | |
| <25 | 2 | ( 0.6) | 2 | 1.14 | 4 | ( 0.9) | 4 | 1.71 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.51 | 3 | ( 0.4) | 3 | 0.89 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site erythema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 2 | ( 0.3) | 3 | 0.89 |
| >=30 - <35 | 0 | | | | 2 | ( 0.3) | 2 | 0.47 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Application site pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Discomfort | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 8 | 3.12 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 3 | ( 0.7) | 3 | 0.90 |
| Missing | 0 | | | | 0 | | | |
| Injection site pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 4 | ( 0.9) | 4 | 1.49 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 7 | ( 0.9) | 25 | 3.63 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chills | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Feeling hot | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site hypersensitivity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site haemorrhage | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.5) | 2 | 0.78 |
| Missing | 0 | | | | 0 | | | |
| Peripheral swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 3 | 0.73 | 4 | ( 0.7) | 4 | 0.93 |
| >=35 | 2 | ( 0.5) | 2 | 0.46 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oedema due to renal disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site urticaria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.51 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Medical device site irritation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Application site bruise | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Axillary pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Condition aggravated | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cyst | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Death | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Drug intolerance | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.49 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Early satiety | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Facial pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Feeling abnormal | | | | | | | | |
| <25 | 1 | ( 0.2) | 3 | 0.71 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.62 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Hernia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hyperthermia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Implant site pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site bruising | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Injection site dermatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site haematoma | | | | | | | | |
| <25 | 2 | ( 0.5) | 6 | 2.73 | 1 | ( 0.2) | 5 | 1.98 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.44 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site hypertrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site induration | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Injection site oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site pruritus | | | | | | | | |
| <25 | 3 | ( 0.8) | 18 | 7.97 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site rash | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Localised oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site dermatitis | | | | | | | | |
| <25 | 6 | ( 1.6) | 6 | 2.83 | 6 | ( 1.4) | 7 | 2.50 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 4 | 0.53 |
| >=30 - <35 | 1 | ( 0.2) | 4 | 0.66 | 2 | ( 0.4) | 5 | 0.91 |
| >=35 | 0 | | | | 2 | ( 0.4) | 2 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Medical device site eczema | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site hypersensitivity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.47 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Multiple organ dysfunction syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Non-cardiac chest pain | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 3 | 0.72 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Oedema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Procedural failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Systemic inflammatory response syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thirst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 2 | ( 0.5) | 2 | 0.62 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site erythema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Vaccination site inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vessel puncture site bruise | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Xerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| **Injury, poisoning and procedural complications** | | | | | | | | |
| **All** | | | | | | | | |
| <25 | 35 | ( 8.7) | 43 | 16.02 | 39 | ( 9.0) | 51 | 18.84 |
| >=25 - <30 | 68 | ( 9.2) | 84 | 15.68 | 63 | ( 8.4) | 75 | 14.69 |
| >=30 - <35 | 59 | ( 9.8) | 70 | 16.66 | 46 | ( 8.0) | 56 | 14.38 |
| >=35 | 32 | ( 7.3) | 44 | 13.38 | 32 | ( 7.6) | 35 | 10.89 |
| Missing | 0 | | | | 0 | | | |
| **Vaccination complication** | | | | | | | | |
| <25 | 4 | ( 1.0) | 4 | 1.61 | 10 | ( 2.3) | 13 | 5.20 |
| >=25 - <30 | 11 | ( 1.5) | 11 | 1.97 | 8 | ( 1.1) | 12 | 2.11 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.76 | 7 | ( 1.2) | 8 | 1.86 |
| >=35 | 2 | ( 0.4) | 6 | 2.16 | 4 | ( 0.9) | 5 | 1.33 |
| Missing | 0 | | | | 0 | | | |
| **Accidental overdose** | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.65 | 0 | | | |
| >=25 - <30 | 9 | ( 1.2) | 10 | 2.40 | 2 | ( 0.3) | 2 | 0.46 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.95 | 2 | ( 0.3) | 3 | 0.95 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| **Fall** | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.90 | 2 | ( 0.5) | 3 | 0.72 |
| >=25 - <30 | 6 | ( 0.8) | 6 | 1.00 | 4 | ( 0.5) | 4 | 0.97 |
| >=30 - <35 | 6 | ( 1.0) | 6 | 1.26 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 5 | ( 1.1) | 5 | 1.44 | 3 | ( 0.7) | 3 | 0.88 |
| Missing | 0 | | | | 0 | | | |
| **Contusion** | | | | | | | | |
| <25 | 4 | ( 1.0) | 4 | 1.50 | 2 | ( 0.5) | 2 | 0.69 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.62 | 5 | ( 0.7) | 5 | 0.93 |
| >=30 - <35 | 5 | ( 0.8) | 6 | 1.21 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 2 | ( 0.4) | 2 | 0.58 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| **Ligament sprain** | | | | | | | | |
| <25 | 6 | ( 1.6) | 6 | 2.63 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.73 | 4 | ( 0.5) | 4 | 0.70 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 3 | ( 0.5) | 3 | 0.76 |
| >=35 | 2 | ( 0.5) | 2 | 0.62 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| **Skin laceration** | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.52 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.64 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Skin abrasion | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.66 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 4 | 0.98 | 2 | ( 0.3) | 2 | 0.47 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 3 | ( 0.5) | 3 | 0.84 |
| >=35 | 3 | ( 0.7) | 5 | 1.21 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Upper limb fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.38 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Incorrect dose administered | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.76 | 3 | ( 0.4) | 4 | 0.79 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.62 | 1 | ( 0.2) | 2 | 0.58 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Rib fracture | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 2 | ( 0.5) | 2 | 0.79 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Limb injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.73 | 3 | ( 0.5) | 4 | 1.06 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Procedural pain | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.57 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prescribed overdose | | | | | | | | |
| <25 | 2 | ( 0.6) | 2 | 1.14 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.51 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Craniocerebral injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Subcutaneous haematoma | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medication error | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.82 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Ankle fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Burn oral cavity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cervical vertebral fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injury | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Joint injury | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.72 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Meniscus injury | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 0 | | | | 2 | ( 0.3) | 2 | 0.33 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Overdose | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Post procedural haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thermal burn | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Accidental underdose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Back injury | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone contusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Femoral neck fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Foot fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Hand fracture | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.77 | 0 | | | |
| >=35 | 2 | ( 0.4) | 2 | 0.71 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hip fracture | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inflammation of wound | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Penile contusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural haematuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Radius fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Road traffic accident | | | | | | | | |
| <25 | 3 | ( 0.8) | 4 | 1.82 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epicondylitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Product administration error | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Product dispensing error | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anaemia postoperative | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Animal bite | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.50 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Animal scratch | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arthropod bite | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.58 | 2 | ( 0.3) | 2 | 0.45 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Arthropod sting | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.64 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Burns first degree | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| Missing | 0 | | | | 0 | | | |
| Chillblains | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Clavicle fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Concussion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.3) | 2 | 0.58 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Corneal abrasion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Crush injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Deafness traumatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Endotracheal intubation complication | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Exposure to SARS-CoV-2 | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Extra dose administered | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Face injury | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Facial bones fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Fibula fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gun shot wound | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Head injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Heat illness | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 2 | 0.53 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Heat stroke | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Humerus fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Injury of conjunctiva | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intentional overdose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intentional product use issue | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ligament rupture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.57 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lower limb fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Multiple injuries | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle contusion | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle strain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.60 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Neck injury | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nerve injury | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Periprocedural myocardial infarction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural complication | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural fistula | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural hypothyroidism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural stroke | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Post procedural swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post-traumatic neck syndrome | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Procedural complication | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Radiation skin injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scar | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scratch | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Seroma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Soft tissue injury | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal column injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal compression fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Stab wound | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Subdural haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sunburn | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tendon injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tendon rupture | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tibia fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tooth fracture | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 2 | ( 0.4) | 2 | 0.59 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Traumatic haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Underdose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 3 | ( 0.5) | 3 | 0.92 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Wound | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 4 | ( 0.5) | 4 | 0.87 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Wound dehiscence | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Wrist fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Wrong dose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.44 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Wrong product administered | | | | | | | | |
| <25 | 0 | | | | 3 | ( 0.7) | 3 | 1.25 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.59 |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.62 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Nervous system disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 38 | ( 9.8) | 59 | 25.94 | 29 | ( 6.7) | 87 | 35.02 |
| >=25 - <30 | 65 | ( 8.9) | 97 | 17.98 | 80 | (10.7) | 105 | 20.00 |
| >=30 - <35 | 66 | (10.9) | 85 | 18.74 | 53 | ( 9.3) | 83 | 19.66 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 38 | ( 8.6) | 57 | 17.75 | 45 | (10.4) | 51 | 15.20 |
| Missing | 0 | | | | 0 | | | |
| Headache | | | | | | | | |
| <25 | 13 | ( 3.4) | 16 | 7.52 | 9 | ( 2.1) | 11 | 4.05 |
| >=25 - <30 | 24 | ( 3.2) | 32 | 5.91 | 24 | ( 3.2) | 28 | 5.89 |
| >=30 - <35 | 21 | ( 3.5) | 27 | 7.05 | 19 | ( 3.3) | 29 | 6.69 |
| >=35 | 12 | ( 2.7) | 17 | 5.63 | 12 | ( 2.9) | 12 | 3.86 |
| Missing | 0 | | | | 0 | | | |
| Dizziness | | | | | | | | |
| <25 | 7 | ( 1.8) | 11 | 4.67 | 6 | ( 1.4) | 7 | 2.77 |
| >=25 - <30 | 10 | ( 1.4) | 10 | 1.64 | 13 | ( 1.7) | 15 | 2.78 |
| >=30 - <35 | 12 | ( 2.0) | 15 | 3.09 | 12 | ( 2.1) | 15 | 3.63 |
| >=35 | 11 | ( 2.5) | 15 | 4.53 | 8 | ( 1.8) | 10 | 2.83 |
| Missing | 0 | | | | 0 | | | |
| Sciatica | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 8 | ( 1.1) | 8 | 1.70 | 7 | ( 0.9) | 7 | 1.11 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 2 | 0.36 |
| >=35 | 2 | ( 0.5) | 2 | 0.59 | 3 | ( 0.7) | 3 | 0.86 |
| Missing | 0 | | | | 0 | | | |
| Tremor | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.80 | 1 | ( 0.2) | 48 | 20.55 |
| >=25 - <30 | 6 | ( 0.8) | 7 | 1.15 | 6 | ( 0.8) | 9 | 2.11 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 3 | 0.74 |
| >=35 | 3 | ( 0.7) | 3 | 0.75 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Diabetic neuropathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 1.10 | 6 | ( 0.8) | 6 | 1.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 2 | ( 0.3) | 2 | 0.45 |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.66 |
| Missing | 0 | | | | 0 | | | |
| Migraine | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.65 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 3 | ( 0.4) | 4 | 0.88 | 2 | ( 0.3) | 2 | 0.52 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.76 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Post herpetic neuralgia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Syncope | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 4 | ( 1.0) | 4 | 1.16 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tension headache | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 3 | 0.52 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoaesthesia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.47 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 5 | 0.90 | 6 | ( 0.8) | 7 | 1.11 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.90 | 3 | ( 0.5) | 3 | 0.98 |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Carpal tunnel syndrome | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.88 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.37 | 3 | ( 0.4) | 3 | 0.60 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 0.97 | 3 | ( 0.5) | 3 | 0.74 |
| >=35 | 2 | ( 0.5) | 2 | 0.49 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Paraesthesia | | | | | | | | |
| <25 | 1 | ( 0.2) | 2 | 0.46 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 4 | ( 0.5) | 4 | 0.79 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.60 |
| >=35 | 3 | ( 0.7) | 3 | 0.87 | 6 | ( 1.4) | 6 | 1.81 |
| Missing | 0 | | | | 0 | | | |
| Dysgeusia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.36 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Burning sensation | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Neuralgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Peripheral paralysis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Somnolence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vascular headache | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Balance disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lumbar radiculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Memory impairment | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Amnesia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cluster headache | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Intracranial pressure increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Speech disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ageusia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anosmia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Autonomic nervous system imbalance | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Basilar migraine | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Brain injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carotid arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carotid artery aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carotid artery stenosis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral artery embolism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cerebral atrophy | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral infarction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Cerebrovascular accident | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebrovascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cervical radiculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cervicobrachial syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.59 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cognitive disorder | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dementia Alzheimer's type | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Disturbance in attention | | | | | | | | |
| <25 | 1 | ( 0.3) | 9 | 5.12 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dizziness postural | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Encephalopathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Essential tremor | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Facial nerve disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Facial paralysis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemorrhage intracranial | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hemiparesis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoglycaemic coma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoglycaemic seizure | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoglycaemic unconsciousness | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyporeflexia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypotonia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ischaemic stroke | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lethargy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Loss of consciousness | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mental impairment | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Meralgia paraesthetica | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Morton's neuralgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myelopathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neuroglycopenia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 3 | 0.79 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neuropathy peripheral | | | | | | | | |
| <25 | 1 | ( 0.3) | 2 | 0.91 | 3 | ( 0.7) | 3 | 1.06 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 4 | ( 0.7) | 4 | 0.82 |
| >=35 | 3 | ( 0.7) | 3 | 0.97 | 2 | ( 0.5) | 2 | 0.65 |
| Missing | 0 | | | | 0 | | | |
| Ophthalmic migraine | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Orthostatic tremor | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Parkinsonian gait | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Piriformis syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Presyncope | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Radiculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Restless legs syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus headache | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| Missing | 0 | | | | 0 | | | |
| Sleep deficit | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thalamic infarction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombotic stroke | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Transient ischaemic attack | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.61 | 0 | | | |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Trigeminal neuralgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vascular encephalopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vertebral artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| White matter lesion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 40 | (10.2) | 50 | 20.28 | 40 | ( 9.3) | 47 | 17.39 |
| >=25 - <30 | 65 | ( 8.8) | 84 | 17.13 | 61 | ( 8.2) | 83 | 16.59 |
| >=30 - <35 | 37 | ( 6.2) | 49 | 11.18 | 47 | ( 8.1) | 65 | 16.47 |
| >=35 | 34 | ( 7.5) | 42 | 12.75 | 32 | ( 7.9) | 41 | 14.59 |
| Missing | 0 | | | | 0 | | | |
| Diabetic retinopathy | | | | | | | | |
| <25 | 18 | ( 4.7) | 20 | 9.07 | 17 | ( 4.0) | 17 | 6.16 |
| >=25 - <30 | 23 | ( 3.1) | 26 | 5.62 | 26 | ( 3.5) | 27 | 5.65 |
| >=30 - <35 | 10 | ( 1.7) | 10 | 2.40 | 15 | ( 2.6) | 16 | 4.33 |
| >=35 | 13 | ( 2.8) | 14 | 4.46 | 14 | ( 3.5) | 16 | 6.12 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Cataract | | | | | | | | |
| <25 | 5 | ( 1.2) | 6 | 1.97 | 3 | ( 0.7) | 3 | 1.08 |
| >=25 - <30 | 12 | ( 1.6) | 13 | 2.52 | 11 | ( 1.5) | 12 | 2.13 |
| >=30 - <35 | 7 | ( 1.2) | 9 | 1.75 | 7 | ( 1.2) | 8 | 1.79 |
| >=35 | 4 | ( 0.9) | 5 | 1.28 | 6 | ( 1.4) | 7 | 2.00 |
| Missing | 0 | | | | 0 | | | |
| Retinopathy hypertensive | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 4 | ( 0.5) | 5 | 0.87 | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 0 | | | | 2 | ( 0.3) | 2 | 0.58 |
| >=35 | 3 | ( 0.6) | 3 | 1.05 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vision blurred | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.64 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 4 | ( 0.7) | 4 | 0.94 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic retinal oedema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.75 | 3 | ( 0.4) | 3 | 0.56 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 2 | ( 0.3) | 2 | 0.45 |
| >=35 | 2 | ( 0.4) | 2 | 0.72 | 4 | ( 1.0) | 5 | 2.04 |
| Missing | 0 | | | | 0 | | | |
| Ocular hyperaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 3 | 0.73 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.61 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.46 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.25 | 2 | ( 0.3) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Posterior capsule opacification | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Dry eye | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.66 | 2 | ( 0.5) | 2 | 0.69 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 3 | ( 0.4) | 3 | 0.49 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 3 | ( 0.7) | 3 | 0.69 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Dry age-related macular degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myopia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 3 | ( 0.4) | 3 | 0.56 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ocular hypertension | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 2 | 0.86 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal exudates | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal vein occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctivitis allergic | | | | | | | | |
| <25 | 1 | ( 0.2) | 2 | 0.47 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Non-proliferative retinopathy | | | | | | | | |
| <25 | 0 | | | | 3 | ( 0.7) | 3 | 1.25 |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.49 | 1 | ( 0.1) | 1 | 0.22 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): OTMTDURY BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD BMIG1BL; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.4) | 2 | 0.76 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acquired epiblepharon | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asthenopia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blepharitis | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.92 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival haemorrhage | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.99 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal tear | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diplopia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Retinal deposits | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Angle closure glaucoma | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival hyperaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Glaucoma | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 2 | ( 0.4) | 2 | 0.86 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.56 |
| Missing | 0 | | | | 0 | | | |
| Maculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous opacities | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cataract nuclear | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epiretinal membrane | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.54 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Age-related macular degeneration | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Amaurosis fugax | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arteriosclerotic retinopathy | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Astigmatism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 3 | ( 0.4) | 3 | 0.64 |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.33 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Chorioretinal atrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival erosion | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival suffusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Corneal bleeding | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Corneal erosion | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cystoid macular oedema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dacryoadenitis acquired | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye discharge | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye inflammation | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Eye irritation | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.61 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eyelid oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hypermetropia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Lacrimation increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Macular degeneration | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Macular hole | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Macular oedema | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.99 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 6 | ( 1.0) | 7 | 1.87 | 0 | | | |
| >=35 | 4 | ( 0.9) | 4 | 1.29 | 3 | ( 0.7) | 3 | 0.91 |
| Missing | 0 | | | | 0 | | | |
| Meibomianitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Normal tension glaucoma | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Ocular ischaemic syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Open angle glaucoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.58 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ophthalmic vein thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Optic disc haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Optic disc vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Photophobia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Photopsia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post thrombotic retinopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Presbyopia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.51 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pterygium | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Retinal degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal detachment | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal drusen | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal scar | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinopathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scintillating scotoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Uveitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Visual acuity reduced | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Visual impairment | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 9 | 2.61 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous detachment | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.86 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous floaters | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.52 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous haemorrhage | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metabolism and nutrition disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 24 | ( 6.0) | 28 | 9.63 | 25 | ( 5.9) | 31 | 11.33 |
| >=25 - <30 | 52 | ( 7.1) | 69 | 12.17 | 53 | ( 7.1) | 72 | 11.71 |
| >=30 - <35 | 27 | ( 4.5) | 33 | 7.02 | 31 | ( 5.4) | 36 | 8.47 |
| >=35 | 29 | ( 6.8) | 33 | 8.97 | 25 | ( 6.0) | 30 | 9.58 |
| Missing | 0 | | | | 0 | | | |
| Hypoglycaemia | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.26 | 8 | ( 1.9) | 13 | 5.17 |
| >=25 - <30 | 12 | ( 1.6) | 20 | 4.38 | 12 | ( 1.6) | 23 | 3.69 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.62 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 2 | ( 0.4) | 3 | 0.66 |
| Missing | 0 | | | | 0 | | | |
| Dyslipidaemia | | | | | | | | |
| <25 | 7 | ( 1.8) | 8 | 3.01 | 4 | ( 0.9) | 4 | 1.44 |
| >=25 - <30 | 9 | ( 1.3) | 9 | 1.55 | 7 | ( 0.9) | 7 | 1.21 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.73 | 4 | ( 0.7) | 4 | 1.10 |
| >=35 | 2 | ( 0.5) | 2 | 0.52 | 2 | ( 0.5) | 2 | 0.88 |
| Missing | 0 | | | | 0 | | | |
| Vitamin B12 deficiency | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.69 | 0 | | | |
| >=25 - <30 | 6 | ( 0.8) | 6 | 0.76 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vitamin D deficiency | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.46 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 6 | ( 0.8) | 6 | 0.90 | 8 | ( 1.1) | 8 | 1.21 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.81 | 4 | ( 0.7) | 4 | 0.94 |
| >=35 | 5 | ( 1.2) | 5 | 1.21 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hyperlipidaemia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.99 | 2 | ( 0.3) | 2 | 0.35 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.49 | 6 | ( 1.1) | 6 | 1.42 |
| >=35 | 5 | ( 1.2) | 5 | 1.43 | 5 | ( 1.1) | 5 | 1.11 |
| Missing | 0 | | | | 0 | | | |
| Hypertriglyceridaemia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.69 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.42 | 2 | ( 0.3) | 2 | 0.27 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.95 | 2 | ( 0.3) | 2 | 0.47 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 3 | ( 0.8) | 3 | 1.34 |
| Missing | 0 | | | | 0 | | | |
| Hyperkalaemia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.69 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.51 | 6 | ( 0.8) | 6 | 1.19 |
| >=30 - <35 | 3 | ( 0.5) | 4 | 0.77 | 3 | ( 0.5) | 3 | 0.64 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Decreased appetite | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.90 |
| Missing | 0 | | | | 0 | | | |
| Hyponatraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.46 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Increased appetite | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.61 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.5) | 2 | 0.66 |
| Missing | 0 | | | | 0 | | | |
| Iron deficiency | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.25 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperglycaemia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 2 | ( 0.5) | 2 | 0.69 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 4 | ( 0.5) | 4 | 0.63 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 4 | ( 0.7) | 4 | 0.96 |
| >=35 | 3 | ( 0.7) | 4 | 1.27 | 4 | ( 1.1) | 4 | 1.82 |
| Missing | 0 | | | | 0 | | | |
| Hypokalaemia | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Obesity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.52 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Zinc deficiency | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fluid retention | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Folate deficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gout | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.33 | 3 | ( 0.5) | 4 | 0.69 |
| >=35 | 2 | ( 0.5) | 2 | 0.46 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Magnesium deficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitamin B complex deficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Abnormal weight gain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Appetite disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dehydration | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 2 | 0.86 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Diabetes mellitus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.46 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Diabetes mellitus inadequate control | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrolyte imbalance | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Food craving | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperammonaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypercalcaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypercholesterolaemia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 2 | ( 0.4) | 2 | 0.82 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Hypernatraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperuricaemia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.80 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoalbuminaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Insulin resistance | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lactic acidosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipomatosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Malnutrition | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metabolic acidosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metabolic disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin and subcutaneous tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 23 | ( 5.7) | 24 | 8.84 | 33 | ( 7.5) | 39 | 14.77 |
| >=25 - <30 | 47 | ( 6.3) | 52 | 9.91 | 37 | ( 5.0) | 47 | 9.29 |
| >=30 - <35 | 32 | ( 5.3) | 33 | 7.36 | 35 | ( 6.2) | 43 | 9.07 |
| >=35 | 21 | ( 4.7) | 22 | 6.58 | 23 | ( 5.4) | 26 | 7.39 |
| Missing | 0 | | | | 0 | | | |
| Eczema | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.66 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.88 | 3 | ( 0.4) | 3 | 0.75 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.49 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Dermatitis contact | | | | | | | | |
| <25 | 0 | | | | 4 | ( 0.9) | 4 | 1.71 |
| >=25 - <30 | 5 | ( 0.7) | 6 | 1.07 | 6 | ( 0.8) | 6 | 1.21 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 4 | ( 0.7) | 4 | 0.83 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urticaria | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.46 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.84 | 7 | ( 1.0) | 7 | 1.34 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.36 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Alopecia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.89 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 3 | ( 0.7) | 3 | 0.90 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dermatitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.76 | 3 | ( 0.4) | 3 | 0.56 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.61 | 4 | ( 0.7) | 5 | 1.28 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pruritus | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 2 | ( 0.4) | 2 | 0.82 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.37 | 4 | ( 0.5) | 4 | 0.61 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.50 | 4 | ( 0.7) | 4 | 0.93 |
| >=35 | 2 | ( 0.5) | 2 | 0.62 | 2 | ( 0.5) | 2 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Rash | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 3 | ( 0.4) | 3 | 0.48 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.92 | 5 | ( 0.9) | 6 | 1.02 |
| >=35 | 8 | ( 1.8) | 8 | 2.37 | 3 | ( 0.7) | 3 | 0.89 |
| Missing | 0 | | | | 0 | | | |
| Night sweats | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.37 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin ulcer | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.79 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.37 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Cold sweat | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 4 | ( 0.9) | 6 | 2.40 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.46 | 3 | ( 0.4) | 5 | 1.42 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Dermatitis allergic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Skin irritation | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.67 |
| >=25 - <30 | 2 | ( 0.3) | 3 | 0.53 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rash papular | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperkeratosis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rash erythematous | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin odour abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Angioedema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dry skin | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 1.04 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.68 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lipodystrophy acquired | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Psoriasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin fissures | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Erythema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ingrowing nail | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.5) | 2 | 0.50 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Livedo reticularis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hidradenitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Skin lesion | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Xeroderma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acne | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Actinic keratosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Alopecia areata | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asteatosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blister | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.59 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic spontaneous urticaria | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cold urticaria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Decubitus ulcer | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dermal cyst | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Dermatitis atopic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic foot | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Drug eruption | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ecchymosis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Granuloma annulare | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemorrhage subcutaneous | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperhidrosis | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.15 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.91 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ingrown hair | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intertrigo | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lentigo | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Leukoplakia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lichen sclerosus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipohypertrophy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Macule | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Miliaria | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.85 | 2 | ( 0.5) | 2 | 0.53 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Myxoid cyst | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nail bed inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neurodermatitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pruritus allergic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Purpura | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rash maculo-papular | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Seborrhoea | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Skin discolouration | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin exfoliation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Telangiectasia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Umbilical haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urticaria contact | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urticaria thermal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 26 | ( 6.6) | 33 | 12.30 | 27 | ( 6.2) | 30 | 11.55 |
| >=25 - <30 | 37 | ( 5.0) | 46 | 9.43 | 44 | ( 5.9) | 62 | 11.71 |
| >=30 - <35 | 39 | ( 6.4) | 49 | 10.38 | 33 | ( 5.8) | 43 | 10.38 |
| >=35 | 30 | ( 6.8) | 49 | 15.07 | 17 | ( 4.0) | 17 | 4.71 |
| Missing | 0 | | | | 1 | | 1 | |
| Oropharyngeal pain | | | | | | | | |
| <25 | 9 | ( 2.3) | 9 | 3.35 | 6 | ( 1.4) | 6 | 2.01 |
| >=25 - <30 | 5 | ( 0.7) | 6 | 1.12 | 6 | ( 0.8) | 8 | 1.42 |
| >=30 - <35 | 6 | ( 1.0) | 7 | 1.61 | 6 | ( 1.1) | 6 | 1.70 |
| >=35 | 4 | ( 1.0) | 4 | 0.95 | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Rhinorrhoea | | | | | | | | |
| <25 | 0 | | | | 5 | ( 1.1) | 5 | 2.10 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 1.24 | 5 | ( 0.7) | 5 | 0.99 |
| >=30 - <35 | 4 | ( 0.7) | 5 | 0.83 | 3 | ( 0.5) | 3 | 0.65 |
| >=35 | 3 | ( 0.7) | 5 | 1.70 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cough | | | | | | | | |
| <25 | 6 | ( 1.5) | 6 | 2.18 | 7 | ( 1.6) | 7 | 2.72 |
| >=25 - <30 | 5 | ( 0.7) | 8 | 1.77 | 8 | ( 1.1) | 9 | 1.77 |
| >=30 - <35 | 9 | ( 1.5) | 9 | 1.77 | 8 | ( 1.4) | 9 | 2.53 |
| >=35 | 6 | ( 1.4) | 6 | 1.79 | 5 | ( 1.1) | 5 | 1.11 |
| Missing | 0 | | | | 0 | | | |
| Dyspnoea | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.69 | 3 | ( 0.7) | 3 | 0.92 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.73 | 3 | ( 0.4) | 3 | 0.50 |
| >=30 - <35 | 0 | | | | 6 | ( 1.0) | 7 | 1.69 |
| >=35 | 3 | ( 0.7) | 3 | 0.92 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Acute respiratory failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.51 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Productive cough | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.86 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus congestion | | | | | | | | |
| <25 | 1 | ( 0.2) | 2 | 0.47 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.49 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Respiratory disorder | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.60 | 2 | ( 0.4) | 2 | 0.86 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.51 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 3 | ( 0.5) | 3 | 0.55 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 2 | ( 0.5) | 2 | 0.92 |
| Missing | 0 | | | | 0 | | | |
| Sleep apnoea syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.49 | 0 | | | |
| >=35 | 3 | ( 0.7) | 3 | 0.81 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asthma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 3 | ( 0.7) | 4 | 1.11 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bronchospasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic obstructive pulmonary disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.55 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dyspnoea exertional | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary fibrosis | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.28 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 3 | ( 0.4) | 3 | 0.57 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pleurisy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal congestion | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.47 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.60 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 4 | ( 0.9) | 4 | 1.08 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 1 | | 1 | |
| Epistaxis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 2 | ( 0.3) | 4 | 0.74 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 4 | ( 0.8) | 8 | 2.88 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rhinitis allergic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 4 | ( 0.5) | 8 | 1.40 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sneezing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.62 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Upper-airway cough syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Acquired diaphragmatic eventration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acute pulmonary oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Allergic bronchitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Allergic cough | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aphonia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bronchial hyperreactivity | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bronchiectasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bronchitis chronic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Dry throat | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysphonia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.44 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Emphysema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemoptysis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hiccups | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Increased viscosity of upper respiratory secretion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Interstitial lung disease | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Laryngeal cyst | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lung disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal dryness | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal obstruction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Nasal septum deviation | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal turbinate hypertrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Paranasal cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Paranasal sinus discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Pleural disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pleural effusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pleuritic pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary congestion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary embolism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary hypertension | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Respiratory failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Respiratory tract inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus pain | | | | | | | | |
| <25 | 1 | ( 0.2) | 2 | 0.47 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Throat irritation | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.82 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Upper respiratory tract inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vascular disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 8 | ( 2.0) | 8 | 2.89 | 8 | ( 1.9) | 9 | 3.03 |
| >=25 - <30 | 31 | ( 4.3) | 34 | 6.02 | 36 | ( 4.8) | 46 | 8.22 |
| >=30 - <35 | 20 | ( 3.3) | 25 | 5.63 | 18 | ( 3.1) | 19 | 4.34 |
| >=35 | 20 | ( 4.6) | 21 | 5.98 | 18 | ( 4.3) | 25 | 7.66 |
| Missing | 0 | | | | 0 | | | |
| Hypertension | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.69 | 4 | ( 1.0) | 4 | 1.35 |
| >=25 - <30 | 16 | ( 2.2) | 16 | 2.95 | 20 | ( 2.7) | 23 | 4.31 |
| >=30 - <35 | 11 | ( 1.8) | 11 | 2.60 | 6 | ( 1.1) | 7 | 1.53 |
| >=35 | 8 | ( 1.8) | 8 | 2.45 | 8 | ( 1.9) | 9 | 2.90 |
| Missing | 0 | | | | 0 | | | |
| Peripheral arterial occlusive disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 4 | 0.65 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Orthostatic hypotension | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Arterial insufficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypotension | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.69 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Varicose ulceration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Hypertensive urgency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral artery stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.28 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 3 | 0.93 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral coldness | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Deep vein thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arteriosclerosis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 4 | ( 0.5) | 4 | 0.70 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Superficial vein thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Venous stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Aortic dilatation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Blood pressure fluctuation | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood pressure inadequately controlled | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Brachiocephalic arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.27 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Flushing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hot flush | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hypertensive crisis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.3) | 3 | 1.38 |
| Missing | 0 | | | | 0 | | | |
| Iliac artery stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Intermittent claudication | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Macroangiopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neovascularisation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral artery aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral ischaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Peripheral vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral venous disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.62 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Phlebitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Thrombophlebitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Varicose vein | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 15 | ( 3.7) | 17 | 6.00 | 15 | ( 3.6) | 18 | 5.65 |
| >=25 - <30 | 31 | ( 4.2) | 44 | 7.59 | 33 | ( 4.4) | 38 | 6.19 |
| >=30 - <35 | 30 | ( 5.0) | 48 | 9.03 | 23 | ( 4.0) | 38 | 8.05 |
| >=35 | 19 | ( 4.5) | 24 | 6.44 | 13 | ( 3.0) | 21 | 6.12 |
| Missing | 0 | | | | 0 | | | |
| Angina pectoris | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 2 | ( 0.5) | 2 | 0.50 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.53 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Supraventricular extrasystoles | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.63 | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Palpitations | | | | | | | | |
| <25 | 0 | | | | 3 | ( 0.7) | 3 | 1.12 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.52 | 3 | ( 0.4) | 3 | 0.50 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.48 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.46 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Coronary artery disease | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.61 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 0.83 | 5 | ( 0.9) | 5 | 0.84 |
| >=35 | 3 | ( 0.7) | 3 | 0.69 | 4 | ( 1.0) | 4 | 1.36 |
| Missing | 0 | | | | 0 | | | |
| Acute myocardial infarction | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 2 | ( 0.5) | 2 | 0.64 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.49 | 3 | ( 0.4) | 3 | 0.48 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 3 | ( 0.5) | 3 | 0.65 |
| >=35 | 3 | ( 0.7) | 3 | 0.87 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ventricular extrasystoles | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.81 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.65 | 1 | ( 0.1) | 2 | 0.26 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.49 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial fibrillation | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 1.04 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 2 | ( 0.3) | 2 | 0.27 |
| >=30 - <35 | 6 | ( 1.0) | 7 | 1.15 | 3 | ( 0.5) | 3 | 0.53 |
| >=35 | 2 | ( 0.5) | 2 | 0.49 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Left ventricular dysfunction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myocardial infarction | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 3 | ( 0.4) | 3 | 0.39 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.58 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Acute coronary syndrome | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Left ventricular hypertrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bundle branch block right | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.4) | 2 | 0.82 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 2 | ( 0.3) | 2 | 0.37 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 3 | 0.53 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac flutter | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mitral valve incompetence | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Mitral valve stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Angina unstable | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac failure chronic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac failure congestive | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.3) | 3 | 0.87 |
| >=35 | 2 | ( 0.5) | 2 | 0.49 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac ventricular thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Coronary artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diastolic dysfunction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arrhythmia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Supraventricular tachycardia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tachycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 6 | ( 0.8) | 6 | 1.07 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiomegaly | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic valve calcification | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Aortic valve incompetence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic valve sclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arteriosclerosis coronary artery | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial enlargement | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial flutter | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Atrioventricular block complete | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Atrioventricular block first degree | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.4) | 2 | 0.58 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bradycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Bundle branch block left | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac arrest | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac dysfunction | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac failure | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 0.83 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 1 | ( 0.3) | 2 | 0.92 |
| Missing | 0 | | | | 0 | | | |
| Cardiac failure acute | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac perfusion defect | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.58 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardio-respiratory arrest | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiovascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic coronary syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Coronary artery stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Left atrial dilatation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Left atrial enlargement | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Myocardial ischaemia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 1 | ( 0.3) | 1 | 0.26 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pericardial effusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pericarditis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus arrhythmia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus bradycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus tachycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Subendocardial ischaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Tricuspid valve incompetence | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Ventricular arrhythmia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ventricular tachycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Investigations | | | | | | | | |
| All | | | | | | | | |
| <25 | 15 | ( 3.7) | 17 | 5.73 | 13 | ( 3.0) | 16 | 6.07 |
| >=25 - <30 | 30 | ( 4.0) | 36 | 6.48 | 31 | ( 4.2) | 34 | 7.11 |
| >=30 - <35 | 28 | ( 4.6) | 30 | 7.26 | 21 | ( 3.7) | 23 | 4.90 |
| >=35 | 21 | ( 4.6) | 26 | 7.97 | 14 | ( 3.4) | 15 | 4.54 |
| Missing | 0 | | | | 0 | | | |
| Weight increased | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.5) | 2 | 0.66 |
| >=25 - <30 | 6 | ( 0.8) | 6 | 1.02 | 6 | ( 0.8) | 6 | 1.07 |
| >=30 - <35 | 6 | ( 1.0) | 6 | 1.28 | 6 | ( 1.1) | 6 | 1.18 |
| >=35 | 7 | ( 1.5) | 7 | 2.27 | 4 | ( 1.0) | 4 | 1.35 |
| Missing | 0 | | | | 0 | | | |
| Blood creatinine increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.86 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 4 | ( 0.9) | 4 | 1.31 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Alanine aminotransferase increased | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| SARS-CoV-2 test positive | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.88 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.37 | 3 | ( 0.4) | 3 | 0.89 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 3 | ( 0.7) | 3 | 0.97 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood immunoglobulin E increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.25 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Blood cholesterol increased | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aspartate aminotransferase increased | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood creatine phosphokinase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Glycosylated haemoglobin increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 1 | ( 0.2) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| International normalised ratio decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| International normalised ratio increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Transferrin saturation decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Weight decreased | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.47 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Catheterisation cardiac | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood pressure increased | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.50 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 4 | ( 0.6) | 4 | 1.09 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram ST segment abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatic specific antigen increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| QRS axis abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Heart rate increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Hepatic enzyme increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Low density lipoprotein increased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mycobacterium tuberculosis complex test positive | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Amylase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Angiogram | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Antinuclear antibody positive | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arthroscopy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood alkaline phosphatase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.57 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood creatine increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood glucose decreased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood glucose fluctuation | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood glucose increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood potassium increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood pressure decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood testosterone decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.38 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Blood triglycerides increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.96 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood uric acid increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood urine present | | | | | | | | |
| <25 | 1 | ( 0.2) | 3 | 0.69 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Body temperature increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone density decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breath sounds abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carbohydrate antigen 19-9 increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac murmur | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Cardiac stress test abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ejection fraction decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram P wave biphasic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram repolarisation abnormality | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram ST segment depression | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram T wave inversion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eosinophil count increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.74 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Free fatty acids increased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Glomerular filtration rate decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Grip strength decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haematocrit increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemoglobin decreased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemoglobin increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatitis B virus test positive | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| International normalised ratio abnormal | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intraocular pressure increased | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipids abnormal | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipids increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Liver function test abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Liver function test increased | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.4) | 2 | 0.59 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Monocyte count decreased | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Monofilament pressure perception test | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Occult blood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Occult blood positive | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Platelet count decreased | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.79 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Red blood cell count decreased | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thyroid function test abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Transaminases increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Vitamin D decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| White blood cell count decreased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| **Psychiatric disorders** | | | | | | | | |
| All | | | | | | | | |
| <25 | 7 | ( 1.7) | 9 | 2.92 | 9 | ( 2.1) | 10 | 3.86 |
| >=25 - <30 | 21 | ( 2.8) | 22 | 3.64 | 12 | ( 1.6) | 14 | 2.62 |
| >=30 - <35 | 5 | ( 0.8) | 5 | 1.12 | 15 | ( 2.6) | 15 | 3.84 |
| >=35 | 8 | ( 1.7) | 9 | 2.74 | 7 | ( 1.6) | 7 | 1.78 |
| Missing | 0 | | | | 0 | | | |
| Insomnia | | | | | | | | |
| <25 | 3 | ( 0.7) | 3 | 0.90 | 0 | | | |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.80 | 4 | ( 0.5) | 5 | 0.94 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 3 | ( 0.6) | 3 | 1.09 | 2 | ( 0.4) | 2 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Anxiety | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 3 | ( 0.7) | 3 | 1.12 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.92 | 5 | ( 0.7) | 5 | 0.98 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sleep disorder | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.82 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.65 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Depression | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.65 | 3 | ( 0.6) | 3 | 1.28 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.28 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 6 | ( 1.0) | 6 | 1.53 |
| >=35 | 2 | ( 0.5) | 2 | 0.46 | 3 | ( 0.7) | 3 | 0.67 |
| Missing | 0 | | | | 0 | | | |
| Adjustment disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adjustment disorder with mixed anxiety and depressed mood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Disorientation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Listless | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Stress | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Depressed mood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adjustment disorder with depressed mood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Affect lability | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Agitation | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anxiety disorder | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Attention deficit hyperactivity disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bruxism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Drug abuse | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Drug dependence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Emotional distress | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fear | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Irritability | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.69 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Major depression | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mental status changes | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mixed anxiety and depressive disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mood swings | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nightmare | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Persistent depressive disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Phobia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post-traumatic stress disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | | | | | |
| All | | | | | | | | |
| <25 | 5 | ( 1.2) | 6 | 1.92 | 4 | ( 0.9) | 5 | 1.92 |
| >=25 - <30 | 17 | ( 2.3) | 20 | 3.75 | 10 | ( 1.3) | 18 | 2.79 |
| >=30 - <35 | 9 | ( 1.5) | 11 | 2.35 | 9 | ( 1.6) | 11 | 2.12 |
| >=35 | 4 | ( 0.9) | 6 | 1.54 | 6 | ( 1.5) | 9 | 3.20 |
| Missing | 0 | | | | 0 | | | |
| Colon adenoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.37 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemangioma of liver | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.39 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adenocarcinoma pancreas | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bladder papilloma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lung cancer metastatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Skin papilloma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Glioblastoma multiforme | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metastases to liver | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral fibroma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Salivary gland neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye naevus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 3 | 0.65 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Small cell lung cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bladder cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colorectal cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acrochordon | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adenocarcinoma of colon | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adrenal adenoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Basal cell carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Benign neoplasm of thyroid gland | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Benign renal neoplasm | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bowen's disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breast cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breast cancer metastatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic myeloid leukaemia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colon cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colon cancer stage II | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysplastic naevus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Endometrial adenocarcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal tract adenoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatocellular carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Invasive breast carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Invasive ductal breast carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Invasive lobular breast carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lipoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lung adenocarcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Lymphangioma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Malignant melanoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Malignant melanoma in situ | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Malignant peritoneal neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Melanocytic naevus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metastases to bone marrow | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metastases to lymph nodes | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myxoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neoplasm skin | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ovarian cancer metastatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic carcinoma | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic carcinoma metastatic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostate cancer | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatic adenoma | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal cell carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal hamartoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Seborrhoeic keratosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.33 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Small intestine neuroendocrine tumour | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Squamous cell carcinoma of skin | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Uterine cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Uterine leiomyoma | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Renal and urinary disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 8 | ( 2.0) | 12 | 4.50 | 7 | ( 1.7) | 7 | 2.35 |
| >=25 - <30 | 15 | ( 2.1) | 18 | 3.55 | 24 | ( 3.2) | 37 | 6.62 |
| >=30 - <35 | 19 | ( 3.1) | 22 | 4.83 | 16 | ( 2.8) | 17 | 3.44 |
| >=35 | 12 | ( 2.8) | 13 | 3.45 | 7 | ( 1.6) | 9 | 2.26 |
| Missing | 0 | | | | 0 | | | |
| Pollakiuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.62 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.57 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nephrolithiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.38 | 3 | ( 0.4) | 5 | 0.92 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ureterolithiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.37 | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysuria | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.36 | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 2 | 0.46 | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Nephrotic syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal cyst | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.34 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 2 | ( 0.4) | 2 | 0.54 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Renal failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal impairment | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 2 | ( 0.3) | 2 | 0.27 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 3 | ( 0.7) | 3 | 0.97 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic kidney disease | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.59 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Haematuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 2 | 0.46 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Microalbuminuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Acute kidney injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 3 | ( 0.4) | 3 | 0.39 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 2 | ( 0.4) | 2 | 0.58 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bladder mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Bladder prolapse | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Calculus urinary | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chromaturia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cystitis haemorrhagic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic nephropathy | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.59 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hydrocalyx | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hydronephrosis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertensive nephropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertonic bladder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Micturition urgency | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nephropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nocturia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Polyuria | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Proteinuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pyelocaliectasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal colic | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.79 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal pain | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.37 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Strangury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Stress urinary incontinence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urethral stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urinary incontinence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Urinary retention | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urinary tract disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urinary tract inflammation | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Urinary tract obstruction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urine odour abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Reproductive system and breast disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 6 | ( 1.5) | 6 | 2.45 | 2 | ( 0.5) | 4 | 1.52 |
| >=25 - <30 | 13 | ( 1.8) | 13 | 2.28 | 9 | ( 1.2) | 9 | 1.79 |
| >=30 - <35 | 6 | ( 1.0) | 6 | 1.36 | 5 | ( 0.9) | 6 | 1.39 |
| >=35 | 8 | ( 1.9) | 8 | 2.17 | 11 | ( 2.6) | 14 | 3.58 |
| Missing | 0 | | | | 0 | | | |
| Benign prostatic hyperplasia | | | | | | | | |
| <25 | 2 | ( 0.5) | 2 | 0.65 | 1 | ( 0.3) | 1 | 0.24 |
| >=25 - <30 | 4 | ( 0.5) | 4 | 0.75 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Breast pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Menstruation delayed | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatic calcification | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Menopausal symptoms | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ovarian cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Uterine prolapse | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Erectile dysfunction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.44 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.49 | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Menstruation irregular | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pelvic discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrophic vulvovaginitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Breast mass | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cervical polyp | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colpocele | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysmenorrhoea | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ectropion of cervix | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ejaculation failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fibrocystic breast disease | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Galactorrhoea | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Genital prolapse | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Intermenstrual bleeding | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.4) | 2 | 0.69 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Menopausal disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ovarian disorder | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Penile pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Penile rash | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.36 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Premenstrual syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatomegaly | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pruritus genital | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Testicular cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Uterine enlargement | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Uterine polyp | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.49 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaginal discharge | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vaginal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Vulvovaginal dryness | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vulvovaginal pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Ear and labyrinth disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 6 | ( 1.5) | 9 | 3.18 | 4 | ( 0.9) | 4 | 1.55 |
| >=25 - <30 | 9 | ( 1.2) | 9 | 1.53 | 6 | ( 0.8) | 6 | 1.07 |
| >=30 - <35 | 9 | ( 1.5) | 9 | 1.61 | 9 | ( 1.6) | 9 | 2.18 |
| >=35 | 4 | ( 0.9) | 4 | 1.21 | 5 | ( 1.1) | 6 | 1.53 |
| Missing | 0 | | | | 0 | | | |
| Vertigo | | | | | | | | |
| <25 | 3 | ( 0.7) | 4 | 1.15 | 3 | ( 0.7) | 3 | 1.12 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.62 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 3 | ( 0.5) | 3 | 0.76 |
| >=35 | 2 | ( 0.5) | 2 | 0.62 | 2 | ( 0.4) | 3 | 0.65 |
| Missing | 0 | | | | 0 | | | |
| Ear pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.27 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.59 | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Ear inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eustachian tube dysfunction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerumen impaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Deafness bilateral | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Deafness neurosensory | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Deafness unilateral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ear discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| External ear pain | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoacusis | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Meniere's disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Middle ear inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Motion sickness | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Presbyacusis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tinnitus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vertigo positional | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood and lymphatic system disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 5 | ( 1.2) | 5 | 1.62 | 4 | ( 0.9) | 4 | 1.44 |
| >=25 - <30 | 9 | ( 1.2) | 9 | 1.86 | 12 | ( 1.6) | 12 | 2.28 |
| >=30 - <35 | 11 | ( 1.8) | 13 | 3.03 | 7 | ( 1.2) | 7 | 1.41 |
| >=35 | 11 | ( 2.6) | 11 | 3.15 | 10 | ( 2.3) | 10 | 2.90 |
| Missing | 0 | | | | 0 | | | |
| Anaemia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 2 | ( 0.5) | 2 | 0.66 |
| >=25 - <30 | 8 | ( 1.1) | 8 | 1.61 | 7 | ( 0.9) | 7 | 1.11 |
| >=30 - <35 | 4 | ( 0.7) | 6 | 1.44 | 0 | | | |
| >=35 | 7 | ( 1.6) | 7 | 2.03 | 5 | ( 1.2) | 5 | 1.58 |
| Missing | 0 | | | | 0 | | | |
| Lymphadenopathy | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.37 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood loss anaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.35 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eosinophilia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypochromic anaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Iron deficiency anaemia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Leukocytosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.3) | 2 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Leukopenia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lymphadenitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.32 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lymphadenopathy mediastinal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Normocytic anaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancytopenia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Polycythaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Splenomegaly | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombocytopenia | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombocytosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Hepatobiliary disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 8 | ( 2.1) | 9 | 3.75 | 3 | ( 0.7) | 5 | 1.99 |
| >=25 - <30 | 8 | ( 1.1) | 11 | 2.19 | 9 | ( 1.2) | 9 | 1.69 |
| >=30 - <35 | 6 | ( 1.0) | 8 | 1.60 | 9 | ( 1.6) | 11 | 2.48 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 2 | ( 0.5) | 3 | 0.69 | 4 | ( 0.9) | 4 | 1.12 |
| Missing | 0 | | | | 0 | | | |
| Hepatic steatosis | | | | | | | | |
| <25 | 2 | ( 0.6) | 2 | 1.14 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 5 | ( 0.7) | 5 | 0.92 | 4 | ( 0.5) | 4 | 0.70 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.49 | 4 | ( 0.7) | 4 | 0.88 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Alcoholic liver disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cholecystitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cholelithiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.17 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gallbladder cholesterolosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gallbladder polyp | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 2 | ( 0.4) | 2 | 0.82 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic calcification | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bile duct stone | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Biliary colic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Biliary dyskinesia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Cholecystitis chronic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gallbladder disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.30 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic cirrhosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic function abnormal | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 1 | ( 0.2) | 1 | 0.39 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hepatic mass | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatomegaly | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperplastic cholecystopathy | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.46 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertransaminasaemia | | | | | | | | |
| <25 | 2 | ( 0.5) | 3 | 1.04 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Liver disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Non-alcoholic steatohepatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nonalcoholic fatty liver disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Steatohepatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Immune system disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 3 | ( 0.8) | 3 | 1.23 | 3 | ( 0.7) | 3 | 1.25 |
| >=25 - <30 | 5 | ( 0.7) | 6 | 1.02 | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.23 | 7 | ( 1.2) | 8 | 2.04 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 4 | ( 0.9) | 4 | 1.09 |
| Missing | 0 | | | | 0 | | | |
| Seasonal allergy | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 3 | ( 0.4) | 3 | 0.50 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.61 | 5 | ( 0.9) | 5 | 1.37 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 2 | ( 0.4) | 2 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Allergy to arthropod bite | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.40 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.14 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.43 |
| Missing | 0 | | | | 0 | | | |
| Food allergy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hypersensitivity | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Allergy to arthropod sting | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anaphylactic reaction | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.42 | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Drug hypersensitivity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Immunisation reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.36 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Congenital, familial and genetic disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.49 | 3 | ( 0.4) | 3 | 0.48 |
| >=30 - <35 | 2 | ( 0.3) | 2 | 0.47 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 2 | ( 0.4) | 2 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Cystic fibrosis lung | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Type V hyperlipidaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.24 | 1 | ( 0.1) | 1 | 0.22 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.35 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial septal defect | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Congenital syphilitic osteochondritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.22 |
| Missing | 0 | | | | 0 | | | |
| Corneal dystrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hydrocele | | | | | | | | |
| <25 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertrophic cardiomyopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Myotonic dystrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Surgical and medical procedures | | | | | | | | |
| All | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.38 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.62 | 3 | ( 0.5) | 3 | 0.78 |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac pacemaker replacement | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.13 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.29 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin neoplasm excision | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.25 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac ablation | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.57 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Knee operation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Large intestinal polypectomy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Removal of foreign body | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Shoulder operation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal operation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Toe amputation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tooth extraction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

Endocrine disorders

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| All | | | | | | | | |
| <25 | 0 | | | | 4 | ( 0.9) | 4 | 1.54 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 8 | ( 1.1) | 8 | 1.24 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 5 | ( 0.9) | 5 | 1.00 |
| >=35 | 4 | ( 1.0) | 4 | 0.98 | 2 | ( 0.5) | 2 | 0.66 |
| Missing | 0 | | | | 0 | | | |
| Hypothyroidism | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.5) | 2 | 0.85 |
| >=25 - <30 | 1 | ( 0.1) | 1 | 0.23 | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Adrenal mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adrenocortical insufficiency acute | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.2) | 1 | 0.43 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.24 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Autoimmune thyroiditis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.23 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Goitre | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.26 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperplasia adrenal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperprolactinaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperthyroidism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.13 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypogonadism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.16 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inappropriate antidiuretic hormone secretion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.30 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Secondary hypogonadism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.44 |
| Missing | 0 | | | | 0 | | | |
| Thyroid mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.35 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.52 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Social circumstances | | | | | | | | |
| All | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Menopause | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

## 7.7.60 Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on- treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Number of subjects | | | | | | | | |
| <25 | 289 | | | | 294 | | | |
| >=25 - <30 | 618 | | | | 645 | | | |
| >=30 - <35 | 554 | | | | 531 | | | |
| >=35 | 419 | | | | 407 | | | |
| Missing | 0 | | | | 1 | | | |
| PYE (years) | | | | | | | | |
| <25 | 226.72 | | | | 224.63 | | | |
| >=25 - <30 | 502.36 | | | | 517.80 | | | |
| >=30 - <35 | 455.36 | | | | 438.19 | | | |
| >=35 | 354.48 | | | | 354.73 | | | |
| Missing | 0.00 | | | | 1.11 | | | |
| Events | | | | | | | | |
| <25 | 177 | (61.0) | 526 | 243.65 | 155 | (52.7) | 411 | 191.32 |
| >=25 - <30 | 369 | (59.8) | 1118 | 232.81 | 380 | (58.9) | 1161 | 232.58 |
| >=30 - <35 | 325 | (58.6) | 1047 | 243.65 | 310 | (58.5) | 948 | 228.08 |
| >=35 | 268 | (63.9) | 787 | 236.79 | 227 | (55.5) | 738 | 225.47 |
| Missing | 0 | | | | 1 | | 1 | |
| Infections and infestations | | | | | | | | |
| All | | | | | | | | |
| <25 | 72 | (24.7) | 100 | 44.75 | 61 | (21.0) | 75 | 33.39 |
| >=25 - <30 | 167 | (27.1) | 233 | 49.28 | 172 | (26.7) | 252 | 51.34 |
| >=30 - <35 | 165 | (29.8) | 236 | 57.10 | 155 | (29.3) | 221 | 51.97 |
| >=35 | 140 | (33.3) | 204 | 61.57 | 135 | (33.0) | 209 | 62.56 |
| Missing | 0 | | | | 0 | | | |
| COVID-19 | | | | | | | | |
| <25 | 17 | ( 5.8) | 17 | 7.15 | 17 | ( 6.0) | 17 | 6.53 |
| >=25 - <30 | 43 | ( 6.9) | 45 | 9.15 | 53 | ( 8.3) | 54 | 9.93 |
| >=30 - <35 | 44 | ( 8.0) | 44 | 10.42 | 36 | ( 6.7) | 36 | 8.56 |
| >=35 | 48 | (11.4) | 49 | 14.69 | 54 | (13.1) | 58 | 17.07 |
| Missing | 0 | | | | 0 | | | |
| Nasopharyngitis | | | | | | | | |
| <25 | 18 | ( 6.1) | 22 | 9.90 | 13 | ( 4.4) | 14 | 6.83 |
| >=25 - <30 | 26 | ( 4.2) | 31 | 6.38 | 27 | ( 4.2) | 32 | 6.23 |
| >=30 - <35 | 26 | ( 4.7) | 29 | 7.39 | 23 | ( 4.4) | 27 | 7.01 |
| >=35 | 13 | ( 3.1) | 17 | 5.55 | 16 | ( 4.0) | 19 | 6.25 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Upper respiratory tract infection | | | | | | | | |
| <25 | 9 | ( 3.1) | 9 | 4.17 | 4 | ( 1.4) | 4 | 1.64 |
| >=25 - <30 | 17 | ( 2.8) | 22 | 4.24 | 17 | ( 2.6) | 19 | 4.14 |
| >=30 - <35 | 19 | ( 3.4) | 23 | 5.16 | 11 | ( 2.1) | 11 | 2.45 |
| >=35 | 17 | ( 4.1) | 21 | 6.29 | 13 | ( 3.1) | 14 | 3.90 |
| Missing | 0 | | | | 0 | | | |
| Influenza | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 4 | ( 1.3) | 4 | 2.05 |
| >=25 - <30 | 12 | ( 2.0) | 13 | 3.30 | 12 | ( 1.8) | 14 | 3.64 |
| >=30 - <35 | 9 | ( 1.7) | 10 | 3.07 | 9 | ( 1.7) | 10 | 2.57 |
| >=35 | 6 | ( 1.4) | 7 | 2.30 | 3 | ( 0.8) | 3 | 1.41 |
| Missing | 0 | | | | 0 | | | |
| Urinary tract infection | | | | | | | | |
| <25 | 6 | ( 2.1) | 6 | 2.59 | 2 | ( 0.7) | 2 | 0.71 |
| >=25 - <30 | 11 | ( 1.8) | 12 | 2.75 | 17 | ( 2.7) | 19 | 3.61 |
| >=30 - <35 | 12 | ( 2.2) | 14 | 3.42 | 16 | ( 3.0) | 18 | 4.15 |
| >=35 | 8 | ( 1.9) | 8 | 2.43 | 9 | ( 2.1) | 9 | 2.53 |
| Missing | 0 | | | | 0 | | | |
| Bronchitis | | | | | | | | |
| <25 | 4 | ( 1.4) | 4 | 2.52 | 3 | ( 1.0) | 3 | 1.26 |
| >=25 - <30 | 11 | ( 1.8) | 11 | 2.35 | 5 | ( 0.8) | 5 | 1.20 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.36 | 5 | ( 0.9) | 5 | 1.08 |
| >=35 | 6 | ( 1.5) | 7 | 1.88 | 4 | ( 1.0) | 4 | 1.16 |
| Missing | 0 | | | | 0 | | | |
| Gastroenteritis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 8 | ( 1.3) | 8 | 1.98 | 8 | ( 1.2) | 9 | 2.19 |
| >=30 - <35 | 9 | ( 1.6) | 9 | 2.51 | 4 | ( 0.7) | 4 | 1.02 |
| >=35 | 8 | ( 1.9) | 8 | 2.46 | 3 | ( 0.8) | 3 | 1.13 |
| Missing | 0 | | | | 0 | | | |
| Pneumonia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 1.30 | 0 | | | |
| >=25 - <30 | 5 | ( 0.8) | 5 | 1.18 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.17 | 4 | ( 0.7) | 4 | 1.00 |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pharyngitis | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.98 | 1 | ( 0.3) | 2 | 1.12 |
| >=25 - <30 | 5 | ( 0.8) | 5 | 0.92 | 7 | ( 1.1) | 7 | 1.45 |
| >=30 - <35 | 7 | ( 1.3) | 8 | 1.73 | 5 | ( 0.9) | 6 | 1.41 |
| >=35 | 2 | ( 0.5) | 3 | 0.82 | 4 | ( 0.9) | 5 | 1.38 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Sinusitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 4 | ( 0.7) | 6 | 1.32 | 4 | ( 0.6) | 4 | 0.92 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 7 | ( 1.3) | 8 | 2.05 |
| >=35 | 7 | ( 1.7) | 7 | 2.11 | 5 | ( 1.2) | 7 | 1.62 |
| Missing | 0 | | | | 0 | | | |
| Tooth infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 4 | ( 0.6) | 5 | 1.00 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 2 | ( 0.4) | 3 | 0.77 | 2 | ( 0.4) | 2 | 0.52 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 3 | ( 0.8) | 3 | 1.13 |
| Missing | 0 | | | | 0 | | | |
| COVID-19 pneumonia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.86 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.01 | 7 | ( 1.3) | 7 | 1.59 |
| >=35 | 5 | ( 1.1) | 5 | 1.60 | 2 | ( 0.5) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Fungal infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.73 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.51 |
| >=35 | 2 | ( 0.5) | 3 | 1.02 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctivitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 3 | ( 1.0) | 3 | 1.48 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.61 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vaginal infection | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.72 | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Rhinitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.61 | 4 | ( 0.6) | 6 | 1.34 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 2 | 0.68 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Otitis media | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.60 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.60 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Tonsillitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.60 | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastroenteritis viral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.60 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Cystitis | | | | | | | | |
| <25 | 4 | ( 1.3) | 5 | 1.67 | 3 | ( 1.1) | 3 | 1.11 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 6 | ( 0.9) | 7 | 1.63 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 1.15 | 4 | ( 0.8) | 5 | 1.23 |
| >=35 | 2 | ( 0.4) | 2 | 0.72 | 3 | ( 0.7) | 3 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Herpes zoster | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 4 | ( 1.4) | 4 | 1.66 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.44 | 6 | ( 0.9) | 7 | 1.28 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.87 | 3 | ( 0.6) | 3 | 0.68 |
| >=35 | 3 | ( 0.8) | 3 | 0.78 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Tooth abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.54 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 5 | ( 0.9) | 5 | 1.08 |
| >=35 | 3 | ( 0.7) | 3 | 0.90 | 1 | ( 0.3) | 2 | 0.96 |
| Missing | 0 | | | | 0 | | | |
| Coronavirus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 3 | 0.59 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 3 | 1.18 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Erysipelas | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 2 | 0.91 |
| Missing | 0 | | | | 0 | | | |
| Anal abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cellulitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 3 | ( 0.6) | 3 | 0.69 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 3 | ( 0.8) | 4 | 1.59 |
| Missing | 0 | | | | 0 | | | |
| Ear infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 3 | ( 0.6) | 3 | 0.70 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Tinea versicolour | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Varicella zoster virus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vulvitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Acute sinusitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Genital candidiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Otitis externa | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.5) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Sepsis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Bacterial infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Candida infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Escherichia urinary tract infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Furuncle | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Gingivitis | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 1.16 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 2 | 0.54 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Herpes virus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Laryngopharyngitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.36 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Localised infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Lower respiratory tract infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 1 | ( 0.2) | 3 | 0.59 |
| >=35 | 2 | ( 0.5) | 2 | 0.54 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Onychomycosis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.70 |
| Missing | 0 | | | | 0 | | | |
| Respiratory syncytial virus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tracheitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urethritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 3 | ( 0.5) | 3 | 0.57 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.69 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 2 | ( 0.5) | 2 | 0.60 | 4 | ( 0.9) | 7 | 1.63 |
| Missing | 0 | | | | 0 | | | |
| Vulvovaginal mycotic infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Bacteraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Respiratory tract infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 2 | ( 0.7) | 2 | 0.92 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 6 | ( 1.5) | 6 | 1.77 | 3 | ( 0.7) | 3 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Respiratory tract infection viral | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.98 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 3 | ( 0.5) | 3 | 0.69 |
| >=30 - <35 | 3 | ( 0.5) | 4 | 1.02 | 3 | ( 0.6) | 3 | 0.82 |
| >=35 | 3 | ( 0.6) | 3 | 1.12 | 2 | ( 0.6) | 3 | 1.44 |
| Missing | 0 | | | | 0 | | | |
| Acarodermatitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Clostridium difficile infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Genital infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Laryngitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Abdominal abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Abscess limb | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Appendicitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asymptomatic COVID-19 | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Balanitis candida | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Bartholinitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Body tinea | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Breast abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breast cellulitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Campylobacter gastroenteritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chlamydial infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cholecystitis infective | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic hepatitis C | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic sinusitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Chronic tonsillitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Clostridium difficile colitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dermatophytosis of nail | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic foot infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diverticulitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ear infection fungal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Empyema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Endophthalmitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Enteritis infectious | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epididymitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Escherichia bacteraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.55 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye infection bacterial | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Folliculitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Fungal balanitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fungal skin infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Gangrene | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastroenteritis norovirus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal infection | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.2) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Genital infection fungal | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Giardiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Helicobacter gastritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Helicobacter infection | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Herpes dermatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Herpes simplex | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Herpes zoster infection neurological | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hordeolum | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Infected bite | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Infected dermal cyst | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Infective iritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Kidney infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Labyrinthitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lyme disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mastitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nail infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 2 | 0.48 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Oophoritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Oral candidiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral herpes | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 2 | ( 0.4) | 3 | 0.97 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oropharyngeal candidiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteomyelitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Otitis media acute | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 3 | ( 0.6) | 3 | 0.69 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Otitis media chronic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Paraspinal abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Paronychia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 2 | 0.55 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Parotitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Peri-implantitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pericoronitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Periodontitis | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.32 | 0 | | | |
| >=25 - <30 | 0 | | | | 3 | ( 0.4) | 3 | 0.78 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Peritonsillar abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Pharyngotonsillitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pneumonia viral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural infection | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post-acute COVID-19 syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 2 | 0.48 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Postoperative wound infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary tuberculoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulpitis dental | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.53 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Purulence | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pustule | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pyelonephritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rotavirus infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Salpingitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Sinusitis bacterial | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin bacterial infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Skin candida | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Skin infection | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Soft tissue infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Subcutaneous abscess | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Suspected COVID-19 | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sweat gland infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Tinea cruris | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Tinea infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.63 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tinea pedis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urosepsis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Varicella | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral pharyngitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral rhinitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Viral tracheitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Viral upper respiratory tract infection | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vulvovaginal candidiasis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 2 | 0.54 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Wound infection | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 35 | (12.0) | 59 | 26.22 | 31 | (10.5) | 38 | 18.33 |
| >=25 - <30 | 91 | (14.7) | 126 | 26.81 | 87 | (13.5) | 118 | 23.65 |
| >=30 - <35 | 74 | (13.3) | 124 | 28.32 | 57 | (10.8) | 80 | 20.10 |
| >=35 | 51 | (12.3) | 71 | 20.31 | 46 | (11.2) | 66 | 19.51 |
| Missing | 0 | | | | 0 | | | |
| Diarrhoea | | | | | | | | |
| <25 | 12 | ( 4.2) | 17 | 8.20 | 3 | ( 1.0) | 3 | 1.53 |
| >=25 - <30 | 24 | ( 3.9) | 26 | 5.31 | 23 | ( 3.5) | 23 | 4.99 |
| >=30 - <35 | 27 | ( 4.8) | 36 | 8.17 | 13 | ( 2.5) | 14 | 3.32 |
| >=35 | 21 | ( 5.0) | 23 | 7.02 | 12 | ( 2.9) | 12 | 3.87 |
| Missing | 0 | | | | 0 | | | |
| Nausea | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.93 | 2 | ( 0.7) | 2 | 1.16 |
| >=25 - <30 | 18 | ( 2.9) | 18 | 3.56 | 6 | ( 0.9) | 6 | 1.03 |
| >=30 - <35 | 12 | ( 2.1) | 13 | 2.86 | 10 | ( 1.9) | 12 | 3.05 |
| >=35 | 5 | ( 1.2) | 5 | 1.63 | 9 | ( 2.2) | 9 | 2.74 |
| Missing | 0 | | | | 0 | | | |
| Vomiting | | | | | | | | |
| <25 | 3 | ( 1.1) | 4 | 2.25 | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 10 | ( 1.6) | 13 | 3.26 | 6 | ( 0.9) | 7 | 1.19 |
| >=30 - <35 | 7 | ( 1.3) | 11 | 2.54 | 3 | ( 0.6) | 3 | 0.95 |
| >=35 | 4 | ( 0.9) | 4 | 1.36 | 6 | ( 1.4) | 8 | 2.04 |
| Missing | 0 | | | | 0 | | | |
| Gastrooesophageal reflux disease | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 3 | ( 1.0) | 3 | 1.30 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 6 | ( 1.0) | 6 | 1.19 | 6 | ( 0.9) | 6 | 1.35 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.69 | 5 | ( 1.0) | 5 | 1.23 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Constipation | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.25 | 4 | ( 1.3) | 4 | 2.03 |
| >=25 - <30 | 5 | ( 0.8) | 6 | 1.45 | 5 | ( 0.8) | 5 | 1.09 |
| >=30 - <35 | 4 | ( 0.7) | 6 | 1.58 | 5 | ( 0.9) | 5 | 1.21 |
| >=35 | 4 | ( 1.0) | 4 | 1.12 | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Abdominal pain upper | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 3 | ( 1.1) | 3 | 1.01 |
| >=25 - <30 | 5 | ( 0.8) | 5 | 0.88 | 5 | ( 0.8) | 5 | 0.88 |
| >=30 - <35 | 4 | ( 0.7) | 6 | 1.71 | 4 | ( 0.7) | 4 | 1.15 |
| >=35 | 3 | ( 0.8) | 3 | 0.75 | 3 | ( 0.7) | 4 | 1.17 |
| Missing | 0 | | | | 0 | | | |
| Abdominal pain | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.30 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 4 | ( 0.7) | 4 | 0.99 | 3 | ( 0.5) | 3 | 0.81 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.16 | 9 | ( 1.7) | 10 | 2.55 |
| >=35 | 4 | ( 1.0) | 4 | 1.02 | 5 | ( 1.2) | 5 | 1.41 |
| Missing | 0 | | | | 0 | | | |
| Abdominal distension | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.76 | 3 | ( 0.5) | 3 | 0.70 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Toothache | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.93 | 3 | ( 1.0) | 4 | 2.21 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.76 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.71 | 2 | ( 0.4) | 2 | 0.64 |
| >=35 | 3 | ( 0.8) | 3 | 0.78 | 3 | ( 0.7) | 5 | 2.02 |
| Missing | 0 | | | | 0 | | | |
| Food poisoning | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.60 | 3 | ( 0.5) | 4 | 0.92 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Abdominal discomfort | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 3 | 1.47 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.60 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gastritis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 5 | ( 0.8) | 5 | 0.76 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.49 | 3 | ( 0.6) | 3 | 0.99 |
| >=35 | 2 | ( 0.5) | 2 | 0.60 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Abdominal pain lower | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.48 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic gastritis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 1.14 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Dental caries | | | | | | | | |
| <25 | 4 | ( 1.3) | 5 | 1.65 | 2 | ( 0.7) | 2 | 1.15 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 5 | ( 0.8) | 5 | 1.11 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.54 | 0 | | | |
| >=35 | 2 | ( 0.5) | 3 | 0.78 | 3 | ( 0.7) | 3 | 0.94 |
| Missing | 0 | | | | 0 | | | |
| Hypoaesthesia oral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 4 | 1.09 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dry mouth | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Flatulence | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 2 | ( 0.3) | 2 | 0.52 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hiatus hernia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperaesthesia teeth | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intra-abdominal haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Dyspepsia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 4 | ( 0.6) | 4 | 0.82 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.95 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Gastric polyps | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemorrhoids | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.65 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 2 | ( 0.5) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Noninfective gingivitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haematochezia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Loose tooth | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tooth impacted | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Proctalgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Abdominal wall disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aphthous ulcer | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eructation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric ulcer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gastrointestinal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lip swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Umbilical hernia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acid peptic disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anal fissure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Anal pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Colitis ischaemic | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Colitis microscopic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Crohn's disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic gastropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diverticulum | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diverticulum intestinal | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Duodenitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Enteritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Enterocolitis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 2 | ( 0.4) | 3 | 0.53 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eosinophilic oesophagitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epigastric discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Faeces pale | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Frequent bowel movements | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric dilatation | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric dysplasia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric mucosal hypertrophy | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal angiodysplasia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Gastrointestinal sounds abnormal | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gingival bleeding | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gingival disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemorrhoidal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hyperchlorhydria | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ileus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Impaired gastric emptying | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inguinal hernia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intestinal dilatation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Irritable bowel syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Large intestine polyp | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 4 | ( 0.6) | 5 | 0.88 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Melaena | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Mesenteric panniculitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Odynophagia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oesophageal pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Oesophagitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic duct dilatation | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic failure | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic pseudocyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pancreatitis acute | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatitis chronic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peptic ulcer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Periodontal disease | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 1.15 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Periodontal inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.39 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rectal polyp | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Rectal prolapse | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Small intestinal obstruction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Stomatitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tongue rough | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tooth disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ulcerative gastritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Upper gastrointestinal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vomiting projectile | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 31 | (10.8) | 42 | 21.97 | 34 | (11.5) | 42 | 20.14 |
| >=25 - <30 | 71 | (11.5) | 108 | 21.48 | 76 | (11.8) | 100 | 19.69 |
| >=30 - <35 | 87 | (15.6) | 133 | 29.77 | 71 | (13.5) | 101 | 24.14 |
| >=35 | 57 | (13.7) | 86 | 25.68 | 64 | (15.7) | 95 | 30.29 |
| Missing | 0 | | | | 0 | | | |
| Back pain | | | | | | | | |
| <25 | 10 | ( 3.5) | 11 | 5.85 | 7 | ( 2.4) | 8 | 3.57 |
| >=25 - <30 | 20 | ( 3.3) | 22 | 4.42 | 19 | ( 3.0) | 19 | 4.19 |
| >=30 - <35 | 19 | ( 3.4) | 19 | 4.43 | 17 | ( 3.3) | 18 | 4.85 |
| >=35 | 13 | ( 3.2) | 14 | 3.99 | 18 | ( 4.3) | 19 | 5.97 |
| Missing | 0 | | | | 0 | | | |
| Arthralgia | | | | | | | | |
| <25 | 4 | ( 1.3) | 4 | 1.59 | 7 | ( 2.4) | 7 | 3.39 |
| >=25 - <30 | 13 | ( 2.1) | 17 | 3.46 | 9 | ( 1.4) | 10 | 1.98 |
| >=30 - <35 | 19 | ( 3.4) | 21 | 4.54 | 18 | ( 3.4) | 21 | 5.34 |
| >=35 | 9 | ( 2.1) | 11 | 3.63 | 14 | ( 3.5) | 16 | 5.26 |
| Missing | 0 | | | | 0 | | | |
| Pain in extremity | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 5 | ( 1.6) | 6 | 3.33 |
| >=25 - <30 | 8 | ( 1.3) | 8 | 1.26 | 12 | ( 1.8) | 16 | 3.40 |
| >=30 - <35 | 12 | ( 2.1) | 13 | 2.72 | 6 | ( 1.2) | 6 | 1.45 |
| >=35 | 9 | ( 2.2) | 10 | 2.90 | 8 | ( 1.9) | 9 | 2.53 |
| Missing | 0 | | | | 0 | | | |
| Myalgia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 5 | ( 1.6) | 5 | 2.86 |
| >=25 - <30 | 6 | ( 1.0) | 6 | 1.33 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 1.14 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 3 | ( 0.7) | 3 | 0.85 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Osteoarthritis | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.67 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 6 | ( 1.0) | 7 | 1.36 | 8 | ( 1.3) | 10 | 1.89 |
| >=30 - <35 | 5 | ( 0.9) | 6 | 1.22 | 10 | ( 1.9) | 11 | 2.60 |
| >=35 | 8 | ( 1.9) | 8 | 2.50 | 5 | ( 1.3) | 5 | 1.90 |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc protrusion | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 4 | ( 0.6) | 5 | 0.82 | 2 | ( 0.3) | 2 | 0.52 |
| >=30 - <35 | 1 | ( 0.2) | 4 | 0.72 | 2 | ( 0.4) | 3 | 0.59 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Muscle spasms | | | | | | | | |
| <25 | 4 | ( 1.4) | 6 | 3.57 | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.61 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 10 | ( 1.8) | 10 | 2.34 | 4 | ( 0.8) | 4 | 0.88 |
| >=35 | 6 | ( 1.5) | 6 | 1.94 | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Trigger finger | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.83 | 2 | ( 0.3) | 4 | 0.62 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 3 | ( 0.7) | 3 | 0.88 | 2 | ( 0.5) | 2 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Osteoporosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscular weakness | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 2 | ( 0.3) | 2 | 0.52 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Neck pain | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.98 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 9 | ( 1.6) | 9 | 2.31 | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 4 | ( 0.9) | 4 | 1.16 |
| Missing | 0 | | | | 0 | | | |
| Periarthritis | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.93 | 4 | ( 1.4) | 4 | 1.66 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.69 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Plantar fasciitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.35 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal osteoarthritis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.20 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Tendonitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 5 | ( 0.9) | 7 | 1.73 | 3 | ( 0.6) | 3 | 0.84 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Axillary mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Flank pain | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 0.74 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 3 | 0.68 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Polymyalgia rheumatica | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 3 | 1.34 |
| Missing | 0 | | | | 0 | | | |
| Arthritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 4 | ( 1.0) | 4 | 1.09 | 2 | ( 0.5) | 2 | 0.93 |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal stiffness | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pain in jaw | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tendon disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Back disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Coccydynia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lumbar spinal stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Musculoskeletal chest pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Myositis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Osteopenia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Spinal stenosis | | | | | | | | |
| <25 | 1 | ( 0.4) | 2 | 1.19 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.59 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Synovial cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acquired claw toe | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bursitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.48 | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Diastasis recti abdominis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Foot deformity | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.30 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 2 | ( 0.5) | 3 | 0.85 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Polyarthritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sacroiliitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Arthropathy | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Cervical spinal stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chondropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Costochondritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Dupuytren's contracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Exostosis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.48 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Facet joint syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fibromyalgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fistula | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Groin pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemarthrosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.65 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intervertebral disc space narrowing | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Jaw disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Joint effusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 2 | ( 0.5) | 3 | 0.96 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Joint swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 3 | ( 0.6) | 3 | 0.86 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Limb deformity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mastication disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Meniscopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle contracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Muscle twitching | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Neuropathic arthropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nodal osteoarthritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteochondritis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteochondrosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 3 | ( 0.8) | 3 | 1.19 |
| Missing | 0 | | | | 0 | | | |
| Periostitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Psoriatic arthropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rheumatoid arthritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rotator cuff syndrome | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 4 | ( 0.6) | 4 | 0.61 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.65 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scoliosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Soft tissue swelling | | | | | | | | |
| <25 | 1 | ( 0.4) | 3 | 1.78 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.91 |
| Missing | 0 | | | | 0 | | | |
| Spinal retrolisthesis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Tenosynovitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 4 | ( 0.6) | 4 | 0.62 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 3 | 0.72 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Tenosynovitis stenosans | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Torticollis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Vertebral osteophyte | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nervous system disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 24 | ( 8.3) | 33 | 15.67 | 18 | ( 6.1) | 24 | 11.31 |
| >=25 - <30 | 58 | ( 9.4) | 87 | 18.11 | 72 | (11.2) | 95 | 19.98 |
| >=30 - <35 | 62 | (11.1) | 77 | 17.48 | 50 | ( 9.4) | 80 | 20.03 |
| >=35 | 36 | ( 8.6) | 55 | 17.69 | 43 | (10.2) | 49 | 14.66 |
| Missing | 0 | | | | 0 | | | |
| Headache | | | | | | | | |
| <25 | 7 | ( 2.4) | 8 | 4.18 | 6 | ( 2.0) | 7 | 3.28 |
| >=25 - <30 | 20 | ( 3.2) | 27 | 5.44 | 19 | ( 2.9) | 21 | 4.46 |
| >=30 - <35 | 18 | ( 3.2) | 21 | 5.54 | 18 | ( 3.4) | 28 | 6.82 |
| >=35 | 12 | ( 2.8) | 17 | 5.86 | 11 | ( 2.7) | 11 | 3.44 |
| Missing | 0 | | | | 0 | | | |
| Dizziness | | | | | | | | |
| <25 | 5 | ( 1.8) | 8 | 4.17 | 4 | ( 1.3) | 4 | 2.09 |
| >=25 - <30 | 10 | ( 1.6) | 10 | 1.93 | 13 | ( 2.0) | 15 | 3.26 |
| >=30 - <35 | 12 | ( 2.1) | 15 | 3.34 | 12 | ( 2.3) | 15 | 3.92 |
| >=35 | 11 | ( 2.6) | 15 | 4.72 | 8 | ( 1.9) | 10 | 2.94 |
| Missing | 0 | | | | 0 | | | |
| Sciatica | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 8 | ( 1.3) | 8 | 2.00 | 7 | ( 1.1) | 7 | 1.31 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 1 | ( 0.2) | 2 | 0.39 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 3 | ( 0.7) | 3 | 0.90 |
| Missing | 0 | | | | 0 | | | |
| Tremor | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 6 | ( 1.0) | 7 | 1.34 | 5 | ( 0.8) | 8 | 2.13 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 3 | 0.80 |
| >=35 | 3 | ( 0.8) | 3 | 0.78 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Diabetic neuropathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.99 | 6 | ( 0.9) | 6 | 1.36 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.49 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Post herpetic neuralgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Syncope | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 3 | ( 0.8) | 3 | 0.82 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tension headache | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 3 | 0.61 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoaesthesia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.67 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 5 | 1.06 | 6 | ( 0.9) | 7 | 1.31 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.97 | 2 | ( 0.4) | 2 | 0.66 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Carpal tunnel syndrome | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 1.24 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.43 | 3 | ( 0.5) | 3 | 0.71 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.04 | 3 | ( 0.5) | 3 | 0.80 |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Migraine | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.92 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.43 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Paraesthesia | | | | | | | | |
| <25 | 1 | ( 0.3) | 2 | 0.65 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 4 | ( 0.6) | 4 | 0.93 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 2 | ( 0.4) | 2 | 0.64 |
| >=35 | 3 | ( 0.7) | 3 | 0.90 | 6 | ( 1.5) | 6 | 1.88 |
| Missing | 0 | | | | 0 | | | |
| Dysgeusia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.42 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neuralgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral paralysis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Somnolence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vascular headache | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Balance disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Burning sensation | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Lumbar radiculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Memory impairment | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Amnesia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cluster headache | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intracranial pressure increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ageusia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anosmia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Autonomic nervous system imbalance | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Basilar migraine | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Brain injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carotid arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carotid artery aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carotid artery stenosis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral artery embolism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cerebral atrophy | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebral infarction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Cerebrovascular accident | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerebrovascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cervical radiculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cervicobrachial syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cognitive disorder | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dementia Alzheimer's type | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Disturbance in attention | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dizziness postural | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Essential tremor | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Facial nerve disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Facial paralysis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hemiparesis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoglycaemic coma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyporeflexia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Ischaemic stroke | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lethargy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Loss of consciousness | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mental impairment | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Meralgia paraesthetica | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Morton's neuralgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myelopathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neuroglycopenia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 3 | 1.11 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neuropathy peripheral | | | | | | | | |
| <25 | 1 | ( 0.4) | 2 | 1.28 | 2 | ( 0.7) | 2 | 0.89 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 4 | ( 0.8) | 4 | 0.88 |
| >=35 | 3 | ( 0.7) | 3 | 1.01 | 2 | ( 0.5) | 2 | 0.67 |
| Missing | 0 | | | | 0 | | | |
| Ophthalmic migraine | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Orthostatic tremor | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Parkinsonian gait | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Piriformis syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Presyncope | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Radiculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Restless legs syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sleep deficit | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thalamic infarction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombotic stroke | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Transient ischaemic attack | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.66 | 0 | | | |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Trigeminal neuralgia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vascular encephalopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vertebral artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| White matter lesion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| General disorders and administration site conditions | | | | | | | | |
| All | | | | | | | | |
| <25 | 36 | (12.4) | 68 | 34.29 | 33 | (11.4) | 52 | 23.67 |
| >=25 - <30 | 53 | ( 8.6) | 94 | 21.03 | 49 | ( 7.6) | 88 | 16.58 |
| >=30 - <35 | 62 | (11.2) | 90 | 22.24 | 55 | (10.4) | 76 | 17.50 |
| >=35 | 48 | (11.5) | 61 | 18.51 | 37 | ( 8.9) | 45 | 13.07 |
| Missing | 0 | | | | 0 | | | |
| Pyrexia | | | | | | | | |
| <25 | 10 | ( 3.4) | 10 | 4.16 | 11 | ( 3.8) | 11 | 4.90 |
| >=25 - <30 | 8 | ( 1.3) | 9 | 1.82 | 13 | ( 2.0) | 14 | 2.62 |
| >=30 - <35 | 10 | ( 1.8) | 10 | 2.31 | 7 | ( 1.3) | 8 | 1.88 |
| >=35 | 4 | ( 1.0) | 4 | 1.25 | 6 | ( 1.5) | 6 | 2.28 |
| Missing | 0 | | | | 0 | | | |
| Hunger | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 6 | ( 1.0) | 7 | 1.27 | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site pain | | | | | | | | |
| <25 | 3 | ( 1.0) | 4 | 2.17 | 2 | ( 0.7) | 2 | 1.20 |
| >=25 - <30 | 6 | ( 1.0) | 7 | 1.48 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 3 | ( 0.6) | 3 | 0.71 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Fatigue | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.31 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 6 | ( 1.0) | 6 | 1.09 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 8 | ( 1.5) | 10 | 2.40 | 6 | ( 1.1) | 6 | 1.37 |
| >=35 | 10 | ( 2.4) | 11 | 3.39 | 6 | ( 1.4) | 6 | 1.59 |
| Missing | 0 | | | | 0 | | | |
| Malaise | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.26 | 2 | ( 0.7) | 2 | 0.74 |
| >=25 - <30 | 5 | ( 0.8) | 6 | 1.07 | 7 | ( 1.1) | 10 | 2.09 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 3 | ( 0.6) | 4 | 0.78 |
| >=35 | 4 | ( 1.0) | 5 | 1.33 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site reaction | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 2 | ( 0.7) | 2 | 1.29 | 1 | ( 0.4) | 3 | 1.01 |
| >=25 - <30 | 4 | ( 0.7) | 14 | 3.87 | 3 | ( 0.5) | 3 | 0.57 |
| >=30 - <35 | 6 | ( 1.1) | 10 | 3.07 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 3 | ( 0.7) | 3 | 0.96 | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Oedema peripheral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 4 | ( 0.7) | 4 | 1.01 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 7 | ( 1.2) | 7 | 1.48 | 5 | ( 0.9) | 6 | 1.28 |
| >=35 | 6 | ( 1.4) | 6 | 1.81 | 3 | ( 0.7) | 3 | 0.94 |
| Missing | 0 | | | | 0 | | | |
| Asthenia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.98 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 4 | ( 0.7) | 4 | 0.78 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 4 | ( 0.8) | 4 | 0.90 |
| >=35 | 3 | ( 0.7) | 3 | 0.97 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Chest pain | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.25 | 0 | | | |
| >=25 - <30 | 4 | ( 0.7) | 4 | 0.88 | 3 | ( 0.5) | 3 | 0.46 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.05 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chest discomfort | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.53 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 2 | ( 0.4) | 2 | 0.75 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site erythema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 4 | 1.14 | 3 | ( 0.5) | 3 | 0.47 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Medical device site bruise | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 3 | 0.73 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 2 | 0.54 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gait disturbance | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site erythema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.51 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.53 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 2 | ( 0.5) | 4 | 1.19 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Application site pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Discomfort | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 8 | 4.39 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.94 |
| Missing | 0 | | | | 0 | | | |
| Injection site pain | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 3 | ( 1.0) | 3 | 1.49 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 7 | ( 1.1) | 25 | 4.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 2 | ( 0.4) | 2 | 0.53 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chills | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Feeling hot | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site hypersensitivity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site haemorrhage | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pain | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 4 | ( 0.7) | 5 | 1.48 | 7 | ( 1.3) | 7 | 1.72 |
| >=35 | 3 | ( 0.7) | 3 | 1.02 | 4 | ( 0.9) | 5 | 1.59 |
| Missing | 0 | | | | 0 | | | |
| Peripheral swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 3 | 0.79 | 4 | ( 0.7) | 4 | 1.00 |
| >=35 | 2 | ( 0.5) | 2 | 0.48 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oedema due to renal disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Swelling face | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Application site bruise | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Axillary pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Condition aggravated | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cyst | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Death | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Drug intolerance | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Early satiety | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Facial pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Feeling abnormal | | | | | | | | |
| <25 | 1 | ( 0.3) | 3 | 1.00 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.67 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hernia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Implant site pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Influenza like illness | | | | | | | | |
| <25 | 1 | ( 0.3) | 2 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.91 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.46 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Injection site bruising | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Injection site dermatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site haematoma | | | | | | | | |
| <25 | 2 | ( 0.7) | 6 | 3.84 | 1 | ( 0.3) | 5 | 2.79 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.52 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site hypertrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site induration | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Injection site oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site pruritus | | | | | | | | |
| <25 | 3 | ( 1.1) | 18 | 11.20 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site rash | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injection site urticaria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Localised oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site dermatitis | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.58 | 3 | ( 1.1) | 3 | 1.11 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 4 | 0.62 |
| >=30 - <35 | 1 | ( 0.2) | 4 | 0.71 | 2 | ( 0.4) | 5 | 0.98 |
| >=35 | 0 | | | | 2 | ( 0.4) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Medical device site eczema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site hypersensitivity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site pain | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.51 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medical device site rash | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Multiple organ dysfunction syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Non-cardiac chest pain | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 3 | 1.01 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Oedema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Procedural failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Systemic inflammatory response syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Thirst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 2 | ( 0.5) | 2 | 0.64 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site erythema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vaccination site inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaccination site pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vessel puncture site bruise | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Xerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 29 | (10.0) | 37 | 18.12 | 24 | ( 8.2) | 27 | 12.41 |
| >=25 - <30 | 53 | ( 8.6) | 67 | 15.01 | 55 | ( 8.5) | 73 | 15.98 |
| >=30 - <35 | 33 | ( 6.0) | 44 | 10.35 | 43 | ( 8.0) | 60 | 15.78 |
| >=35 | 32 | ( 7.4) | 40 | 12.48 | 30 | ( 7.6) | 39 | 14.02 |
| Missing | 0 | | | | 0 | | | |
| Diabetic retinopathy | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 12 | ( 4.3) | 14 | 7.96 | 10 | ( 3.5) | 10 | 4.44 |
| >=25 - <30 | 17 | ( 2.8) | 20 | 4.81 | 23 | ( 3.6) | 24 | 5.59 |
| >=30 - <35 | 10 | ( 1.8) | 10 | 2.59 | 12 | ( 2.2) | 13 | 3.47 |
| >=35 | 13 | ( 2.9) | 14 | 4.65 | 13 | ( 3.3) | 15 | 5.79 |
| Missing | 0 | | | | 0 | | | |
| Cataract | | | | | | | | |
| <25 | 4 | ( 1.4) | 5 | 1.97 | 2 | ( 0.7) | 2 | 0.92 |
| >=25 - <30 | 10 | ( 1.6) | 11 | 2.36 | 11 | ( 1.7) | 12 | 2.49 |
| >=30 - <35 | 6 | ( 1.1) | 8 | 1.55 | 6 | ( 1.1) | 7 | 1.53 |
| >=35 | 4 | ( 1.0) | 5 | 1.33 | 6 | ( 1.5) | 7 | 2.08 |
| Missing | 0 | | | | 0 | | | |
| Retinopathy hypertensive | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 3 | ( 0.5) | 4 | 0.72 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.63 |
| >=35 | 3 | ( 0.6) | 3 | 1.09 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ocular hyperaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 3 | 0.85 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.66 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vision blurred | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 4 | ( 0.8) | 4 | 1.02 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.54 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.48 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye pain | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.30 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic retinal oedema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 2 | ( 0.4) | 2 | 0.75 | 4 | ( 1.1) | 5 | 2.12 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Dry age-related macular degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myopia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ocular hypertension | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal exudates | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal vein occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctivitis allergic | | | | | | | | |
| <25 | 1 | ( 0.3) | 2 | 0.67 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Non-proliferative retinopathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.57 | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acquired epiblepharon | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asthenopia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blepharitis | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.30 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival haemorrhage | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Posterior capsule opacification | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal tear | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diplopia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Retinal deposits | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Angle closure glaucoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival hyperaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dry eye | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.93 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 3 | ( 0.5) | 3 | 0.57 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 3 | ( 0.7) | 3 | 0.72 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Glaucoma | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Maculopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous opacities | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Age-related macular degeneration | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Amaurosis fugax | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Arteriosclerotic retinopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Astigmatism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.36 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Cataract nuclear | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chorioretinal atrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival erosion | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Conjunctival suffusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Corneal bleeding | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Corneal erosion | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Cystoid macular oedema | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dacryoadenitis acquired | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epiretinal membrane | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye discharge | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye inflammation | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Eye irritation | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.66 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eyelid oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hypermetropia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Lacrimation increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Macular degeneration | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Macular hole | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Macular oedema | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.99 | 0 | | | |
| >=35 | 4 | ( 0.9) | 4 | 1.35 | 3 | ( 0.8) | 3 | 0.95 |
| Missing | 0 | | | | 0 | | | |
| Meibomianitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Normal tension glaucoma | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ocular ischaemic syndrome | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Open angle glaucoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.63 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ophthalmic vein thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Optic disc haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Optic disc vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Photophobia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post thrombotic retinopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Presbyopia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Retinal aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Retinal degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal detachment | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal drusen | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal scar | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Retinal vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Retinopathy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scintillating scotoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Uveitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Visual acuity reduced | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Visual impairment | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 9 | 2.82 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous degeneration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous detachment | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous floaters | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitreous haemorrhage | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 1 | ( 0.4) | 1 | 0.37 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injury, poisoning and procedural complications | | | | | | | | |
| All | | | | | | | | |
| <25 | 26 | ( 8.8) | 32 | 13.72 | 24 | ( 8.1) | 30 | 13.85 |
| >=25 - <30 | 53 | ( 8.6) | 64 | 12.42 | 52 | ( 8.0) | 64 | 13.40 |
| >=30 - <35 | 53 | ( 9.5) | 64 | 15.91 | 41 | ( 7.7) | 51 | 13.53 |
| >=35 | 32 | ( 7.6) | 44 | 13.93 | 30 | ( 7.3) | 33 | 10.17 |
| Missing | 0 | | | | 0 | | | |
| Vaccination complication | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.67 | 5 | ( 1.7) | 5 | 2.50 |
| >=25 - <30 | 9 | ( 1.5) | 9 | 1.71 | 6 | ( 0.9) | 10 | 1.78 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 6 | ( 1.1) | 7 | 1.61 |
| >=35 | 2 | ( 0.4) | 6 | 2.25 | 4 | ( 0.9) | 5 | 1.38 |
| Missing | 0 | | | | 0 | | | |
| Fall | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.26 | 2 | ( 0.7) | 3 | 1.01 |
| >=25 - <30 | 6 | ( 1.0) | 6 | 1.18 | 3 | ( 0.5) | 3 | 0.79 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.01 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 5 | ( 1.2) | 5 | 1.50 | 3 | ( 0.7) | 3 | 0.92 |
| Missing | 0 | | | | 0 | | | |
| Accidental overdose | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.92 | 0 | | | |
| >=25 - <30 | 4 | ( 0.7) | 4 | 1.02 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 2 | 0.63 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Contusion | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.32 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.73 | 4 | ( 0.6) | 4 | 0.74 |
| >=30 - <35 | 5 | ( 0.9) | 6 | 1.30 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 2 | ( 0.5) | 2 | 0.60 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ligament sprain | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.30 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.85 | 4 | ( 0.6) | 4 | 0.83 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 3 | ( 0.6) | 3 | 0.82 |
| >=35 | 2 | ( 0.5) | 2 | 0.65 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin laceration | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.61 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.69 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Upper limb fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.45 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rib fracture | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 2 | ( 0.7) | 2 | 1.12 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Skin abrasion | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.93 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.56 | 2 | ( 0.3) | 2 | 0.55 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 2 | ( 0.4) | 2 | 0.51 |
| >=35 | 3 | ( 0.8) | 5 | 1.26 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Craniocerebral injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Subcutaneous haematoma | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Medication error | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Ankle fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Burn oral cavity | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cervical vertebral fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Injury | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Joint injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.78 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Limb injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.79 | 3 | ( 0.6) | 4 | 1.15 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Meniscus injury | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Overdose | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Post procedural haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Procedural pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.61 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thermal burn | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Accidental underdose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Back injury | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone contusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Femoral neck fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Foot fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hand fracture | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.48 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 2 | ( 0.4) | 2 | 0.74 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hip fracture | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inflammation of wound | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Penile contusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural haematuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Radius fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Road traffic accident | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Animal bite | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 0.71 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arthropod bite | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.63 | 2 | ( 0.4) | 2 | 0.49 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Arthropod sting | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.69 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Burns first degree | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chillblains | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Concussion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.63 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Crush injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Deafness traumatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Endotracheal intubation complication | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epicondylitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Exposure to SARS-CoV-2 | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Extra dose administered | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Face injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Facial bones fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Fibula fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gun shot wound | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Head injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Heat illness | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 2 | 0.74 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Humerus fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Incorrect dose administered | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 3 | ( 0.5) | 4 | 0.93 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.67 | 1 | ( 0.2) | 2 | 0.63 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Injury of conjunctiva | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intentional overdose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intentional product use issue | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ligament rupture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.61 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lower limb fracture | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Multiple injuries | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle contusion | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Muscle strain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.64 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Neck injury | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Periprocedural myocardial infarction | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural complication | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural fistula | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural hypothyroidism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post procedural stroke | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Post procedural swelling | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post-traumatic neck syndrome | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Procedural complication | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Product administration error | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Radiation skin injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scar | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Scratch | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Seroma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Soft tissue injury | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal column injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal compression fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Stab wound | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Subdural haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sunburn | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tendon injury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tendon rupture | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tibia fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tooth fracture | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Traumatic haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Underdose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 3 | ( 0.6) | 3 | 0.99 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Wound | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 3 | ( 0.5) | 3 | 0.67 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Wrist fracture | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Wrong dose | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.52 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Wrong product administered | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.67 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Metabolism and nutrition disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 22 | ( 7.6) | 26 | 11.95 | 19 | ( 6.5) | 23 | 11.11 |
| >=25 - <30 | 48 | ( 7.7) | 63 | 12.49 | 51 | ( 7.9) | 70 | 13.04 |
| >=30 - <35 | 27 | ( 4.9) | 33 | 7.58 | 30 | ( 5.7) | 35 | 8.74 |
| >=35 | 27 | ( 6.7) | 31 | 8.54 | 25 | ( 6.2) | 30 | 9.97 |
| Missing | 0 | | | | 0 | | | |
| Hypoglycaemia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 5 | ( 1.7) | 9 | 4.86 |
| >=25 - <30 | 9 | ( 1.5) | 15 | 3.64 | 12 | ( 1.8) | 23 | 4.33 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.67 | 1 | ( 0.2) | 1 | 0.18 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 2 | ( 0.5) | 3 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Dyslipidaemia | | | | | | | | |
| <25 | 7 | ( 2.5) | 8 | 4.23 | 4 | ( 1.3) | 4 | 2.03 |
| >=25 - <30 | 9 | ( 1.5) | 9 | 1.82 | 7 | ( 1.1) | 7 | 1.42 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.79 | 4 | ( 0.8) | 4 | 1.19 |
| >=35 | 2 | ( 0.5) | 2 | 0.54 | 2 | ( 0.5) | 2 | 0.91 |
| Missing | 0 | | | | 0 | | | |
| Vitamin B12 deficiency | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 0.98 | 0 | | | |
| >=25 - <30 | 6 | ( 0.9) | 6 | 0.89 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hyperlipidaemia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 5 | ( 0.8) | 5 | 1.17 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.53 | 6 | ( 1.1) | 6 | 1.54 |
| >=35 | 5 | ( 1.2) | 5 | 1.49 | 5 | ( 1.2) | 5 | 1.16 |
| Missing | 0 | | | | 0 | | | |
| Vitamin D deficiency | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.65 | 0 | | | |
| >=25 - <30 | 5 | ( 0.8) | 5 | 0.76 | 7 | ( 1.1) | 7 | 1.07 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.87 | 4 | ( 0.8) | 4 | 1.02 |
| >=35 | 5 | ( 1.3) | 5 | 1.26 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hypertriglyceridaemia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.49 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 1.02 | 2 | ( 0.4) | 2 | 0.51 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 3 | ( 0.8) | 3 | 1.39 |
| Missing | 0 | | | | 0 | | | |
| Hyperkalaemia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.60 | 6 | ( 0.9) | 6 | 1.39 |
| >=30 - <35 | 3 | ( 0.5) | 4 | 0.83 | 3 | ( 0.6) | 3 | 0.69 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Decreased appetite | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.94 |
| Missing | 0 | | | | 0 | | | |
| Hyponatraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.54 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Increased appetite | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.66 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 2 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Iron deficiency | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.30 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperglycaemia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 2 | ( 0.7) | 2 | 0.97 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 4 | ( 0.6) | 4 | 0.74 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 4 | ( 0.8) | 4 | 1.03 |
| >=35 | 3 | ( 0.7) | 4 | 1.32 | 4 | ( 1.1) | 4 | 1.90 |
| Missing | 0 | | | | 0 | | | |
| Hypokalaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Obesity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Zinc deficiency | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fluid retention | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Folate deficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gout | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.35 | 3 | ( 0.6) | 4 | 0.75 |
| >=35 | 2 | ( 0.5) | 2 | 0.48 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Magnesium deficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vitamin B complex deficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Abnormal weight gain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Appetite disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dehydration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Diabetes mellitus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.23 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Diabetes mellitus inadequate control | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrolyte imbalance | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Food craving | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperammonaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypercalcaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypercholesterolaemia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Hypernatraemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperuricaemia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoalbuminaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Insulin resistance | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lactic acidosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipomatosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Malnutrition | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metabolic acidosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metabolic disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Skin and subcutaneous tissue disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 19 | ( 6.5) | 20 | 9.23 | 17 | ( 5.8) | 19 | 8.73 |
| >=25 - <30 | 36 | ( 5.8) | 41 | 8.34 | 29 | ( 4.5) | 35 | 6.71 |
| >=30 - <35 | 27 | ( 4.8) | 28 | 6.22 | 35 | ( 6.6) | 43 | 9.79 |
| >=35 | 17 | ( 4.1) | 18 | 5.27 | 23 | ( 5.6) | 26 | 7.69 |
| Missing | 0 | | | | 0 | | | |
| Eczema | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.93 | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 5 | ( 0.8) | 5 | 1.03 | 2 | ( 0.3) | 2 | 0.53 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.53 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Urticaria | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.65 | 0 | | | |
| >=25 - <30 | 4 | ( 0.7) | 4 | 0.99 | 5 | ( 0.8) | 5 | 0.87 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Dermatitis contact | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 4 | 0.65 | 4 | ( 0.6) | 4 | 0.73 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 4 | ( 0.8) | 4 | 0.90 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Alopecia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 2 | ( 0.5) | 2 | 0.54 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pruritus | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.43 | 4 | ( 0.6) | 4 | 0.72 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.54 | 4 | ( 0.7) | 4 | 1.00 |
| >=35 | 2 | ( 0.5) | 2 | 0.64 | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Rash | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 3 | ( 0.5) | 3 | 0.57 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 5 | ( 0.9) | 6 | 1.10 |
| >=35 | 7 | ( 1.6) | 7 | 2.07 | 3 | ( 0.7) | 3 | 0.93 |
| Missing | 0 | | | | 0 | | | |
| Night sweats | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.43 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin ulcer | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 1.12 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.44 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Cold sweat | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.54 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Dermatitis allergic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Rash papular | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperkeratosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rash erythematous | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin odour abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Angioedema | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dry skin | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.67 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 3 | ( 0.7) | 3 | 0.70 |
| Missing | 0 | | | | 0 | | | |
| Lipodystrophy acquired | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Psoriasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin fissures | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin irritation | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.33 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Erythema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ingrowing nail | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 2 | ( 0.7) | 2 | 0.71 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Livedo reticularis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acne | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Actinic keratosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Alopecia areata | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asteatosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blister | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cold urticaria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Decubitus ulcer | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dermal cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.52 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Dermatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.66 | 4 | ( 0.8) | 5 | 1.39 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic foot | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Drug eruption | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ecchymosis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Granuloma annulare | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemorrhage subcutaneous | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hidradenitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Hyperhidrosis | | | | | | | | |
| <25 | 3 | ( 1.1) | 3 | 1.62 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.99 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Intertrigo | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lentigo | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Leukoplakia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipohypertrophy | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Macule | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Miliaria | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 1.19 | 2 | ( 0.7) | 2 | 0.74 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Myxoid cyst | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nail bed inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neurodermatitis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pruritus allergic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Purpura | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rash maculo-papular | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Seborrhoea | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Skin discolouration | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Skin exfoliation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin lesion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Umbilical haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urticaria contact | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urticaria thermal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vascular disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 7 | ( 2.4) | 7 | 3.26 | 7 | ( 2.4) | 8 | 3.66 |
| >=25 - <30 | 29 | ( 4.7) | 32 | 6.46 | 34 | ( 5.3) | 44 | 8.95 |
| >=30 - <35 | 19 | ( 3.4) | 24 | 5.73 | 17 | ( 3.2) | 18 | 4.29 |
| >=35 | 18 | ( 4.4) | 19 | 5.44 | 18 | ( 4.5) | 25 | 7.97 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hypertension | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 3 | ( 1.0) | 3 | 1.30 |
| >=25 - <30 | 14 | ( 2.3) | 14 | 2.87 | 19 | ( 2.9) | 22 | 4.71 |
| >=30 - <35 | 10 | ( 1.8) | 10 | 2.47 | 5 | ( 1.0) | 6 | 1.25 |
| >=35 | 6 | ( 1.5) | 6 | 1.76 | 8 | ( 2.0) | 9 | 3.02 |
| Missing | 0 | | | | 0 | | | |
| Peripheral arterial occlusive disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 4 | 0.76 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Orthostatic hypotension | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arterial insufficiency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypotension | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Varicose ulceration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Hypertensive urgency | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Peripheral artery stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.33 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 3 | 1.00 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral coldness | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Deep vein thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 4 | ( 0.6) | 4 | 0.83 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Superficial vein thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Venous stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Aortic dilatation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Blood pressure fluctuation | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood pressure inadequately controlled | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Brachiocephalic arteriosclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Flushing | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haematoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hot flush | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertensive crisis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.3) | 3 | 1.44 |
| Missing | 0 | | | | 0 | | | |
| Iliac artery stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Intermittent claudication | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Macroangiopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neovascularisation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Peripheral artery aneurysm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral ischaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral vascular disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Peripheral venous disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.64 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Phlebitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Thrombophlebitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Varicose vein | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| **Respiratory, thoracic and mediastinal disorders** | | | | | | | | |
| All | | | | | | | | |
| <25 | 18 | ( 6.2) | 24 | 10.10 | 15 | ( 5.0) | 15 | 7.21 |
| >=25 - <30 | 28 | ( 4.5) | 33 | 7.18 | 38 | ( 5.9) | 53 | 10.60 |
| >=30 - <35 | 35 | ( 6.2) | 45 | 9.83 | 30 | ( 5.7) | 38 | 9.20 |
| >=35 | 30 | ( 7.1) | 49 | 15.69 | 17 | ( 4.1) | 17 | 4.90 |
| Missing | 0 | | | | 1 | | 1 | |
| Oropharyngeal pain | | | | | | | | |
| <25 | 6 | ( 2.0) | 6 | 2.30 | 5 | ( 1.7) | 5 | 2.23 |
| >=25 - <30 | 5 | ( 0.8) | 6 | 1.32 | 6 | ( 0.9) | 8 | 1.67 |
| >=30 - <35 | 4 | ( 0.7) | 5 | 1.04 | 4 | ( 0.8) | 4 | 1.04 |
| >=35 | 4 | ( 1.0) | 4 | 0.99 | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Dyspnoea | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 3 | ( 1.0) | 3 | 1.29 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.85 | 3 | ( 0.5) | 3 | 0.58 |
| >=30 - <35 | 0 | | | | 6 | ( 1.1) | 7 | 1.82 |
| >=35 | 3 | ( 0.7) | 3 | 0.96 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Rhinorrhoea | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.85 | 3 | ( 0.5) | 3 | 0.46 |
| >=30 - <35 | 4 | ( 0.7) | 5 | 0.89 | 3 | ( 0.6) | 3 | 0.70 |
| >=35 | 3 | ( 0.7) | 5 | 1.77 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acute respiratory failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.60 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cough | | | | | | | | |
| <25 | 5 | ( 1.7) | 5 | 2.27 | 4 | ( 1.3) | 4 | 2.03 |
| >=25 - <30 | 3 | ( 0.5) | 4 | 0.88 | 6 | ( 0.9) | 6 | 1.04 |
| >=30 - <35 | 9 | ( 1.6) | 9 | 1.91 | 5 | ( 0.9) | 6 | 1.53 |
| >=35 | 6 | ( 1.4) | 6 | 1.86 | 5 | ( 1.2) | 5 | 1.16 |
| Missing | 0 | | | | 0 | | | |
| Productive cough | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 2 | ( 0.4) | 2 | 0.52 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Sleep apnoea syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.53 | 0 | | | |
| >=35 | 3 | ( 0.7) | 3 | 0.84 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Asthma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 3 | ( 0.7) | 4 | 1.16 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bronchospasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic obstructive pulmonary disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.59 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dyspnoea exertional | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary fibrosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.33 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 3 | ( 0.5) | 3 | 0.67 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pleurisy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus congestion | | | | | | | | |
| <25 | 1 | ( 0.3) | 2 | 0.67 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal congestion | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.67 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.65 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 4 | ( 1.0) | 4 | 1.12 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 1 | | 1 | |
| Acquired diaphragmatic eventration | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acute pulmonary oedema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Allergic bronchitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Allergic cough | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aphonia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bronchiectasis | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bronchitis chronic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Dry throat | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysphonia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.52 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Emphysema | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Epistaxis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 4 | 0.86 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 4 | ( 0.9) | 8 | 2.99 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemoptysis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Increased viscosity of upper respiratory secretion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Interstitial lung disease | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Laryngeal cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lung disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal dryness | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal obstruction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Nasal septum deviation | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nasal turbinate hypertrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Paranasal cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Paranasal sinus discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pleural disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pleural effusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pleuritic pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary embolism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pulmonary hypertension | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Respiratory disorder | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 3 | ( 0.6) | 3 | 0.59 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 2 | ( 0.6) | 2 | 0.96 |
| Missing | 0 | | | | 0 | | | |
| Respiratory failure | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Respiratory tract inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Rhinitis allergic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 3 | ( 0.5) | 7 | 1.30 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 2 | 0.67 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sneezing | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.65 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Throat irritation | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Upper respiratory tract inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Upper-airway cough syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Cardiac disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 12 | ( 4.1) | 14 | 6.04 | 12 | ( 4.2) | 15 | 6.14 |
| >=25 - <30 | 27 | ( 4.4) | 40 | 7.71 | 32 | ( 5.0) | 37 | 6.92 |
| >=30 - <35 | 28 | ( 5.0) | 46 | 9.06 | 22 | ( 4.1) | 36 | 7.89 |
| >=35 | 19 | ( 4.6) | 24 | 6.70 | 13 | ( 3.2) | 21 | 6.37 |
| Missing | 0 | | | | 0 | | | |
| Angina pectoris | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 0.71 |
| >=25 - <30 | 4 | ( 0.6) | 4 | 0.62 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Supraventricular extrasystoles | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.73 | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Palpitations | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.61 | 3 | ( 0.5) | 3 | 0.59 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Coronary artery disease | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.72 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 0.89 | 5 | ( 0.9) | 5 | 0.91 |
| >=35 | 3 | ( 0.7) | 3 | 0.72 | 4 | ( 1.0) | 4 | 1.42 |
| Missing | 0 | | | | 0 | | | |
| Acute myocardial infarction | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 2 | ( 0.7) | 2 | 0.89 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.57 | 3 | ( 0.5) | 3 | 0.57 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 3 | ( 0.6) | 3 | 0.71 |
| >=35 | 3 | ( 0.7) | 3 | 0.90 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial fibrillation | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.66 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 6 | ( 1.1) | 7 | 1.24 | 3 | ( 0.6) | 3 | 0.57 |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Left ventricular dysfunction | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.45 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myocardial infarction | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 3 | ( 0.5) | 3 | 0.46 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.63 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acute coronary syndrome | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Left ventricular hypertrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac flutter | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mitral valve incompetence | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Mitral valve stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Angina unstable | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Bundle branch block right | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.43 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 3 | 0.57 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac failure chronic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac failure congestive | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 3 | 0.94 |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac ventricular thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Coronary artery occlusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diastolic dysfunction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ventricular extrasystoles | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 2 | 0.31 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.53 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arrhythmia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Supraventricular tachycardia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tachycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 6 | ( 0.9) | 6 | 1.25 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Aortic valve calcification | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Aortic valve incompetence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Aortic valve sclerosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arteriosclerosis coronary artery | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial enlargement | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial flutter | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial thrombosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrioventricular block complete | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Atrioventricular block first degree | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.60 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bradycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Bundle branch block left | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac arrest | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardiac dysfunction | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Cardiac failure | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 0.89 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.63 | 1 | ( 0.3) | 2 | 0.96 |
| Missing | 0 | | | | 0 | | | |
| Cardiac failure acute | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac perfusion defect | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.63 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cardio-respiratory arrest | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic coronary syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Coronary artery stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Left atrial dilatation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Left atrial enlargement | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Myocardial ischaemia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Pericardial effusion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pericarditis | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus arrhythmia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus bradycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sinus tachycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Subendocardial ischaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Tricuspid valve incompetence | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ventricular arrhythmia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ventricular tachycardia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Investigations | | | | | | | | |
| All | | | | | | | | |
| <25 | 13 | ( 4.5) | 15 | 6.46 | 9 | ( 3.0) | 11 | 5.53 |
| >=25 - <30 | 25 | ( 4.0) | 30 | 5.81 | 23 | ( 3.6) | 26 | 5.55 |
| >=30 - <35 | 22 | ( 4.0) | 24 | 5.76 | 20 | ( 3.8) | 21 | 4.49 |
| >=35 | 20 | ( 4.6) | 25 | 7.90 | 14 | ( 3.5) | 15 | 4.73 |
| Missing | 0 | | | | 0 | | | |
| Weight increased | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 2 | ( 0.7) | 2 | 0.93 |
| >=25 - <30 | 5 | ( 0.8) | 5 | 0.89 | 6 | ( 0.9) | 6 | 1.26 |
| >=30 - <35 | 6 | ( 1.1) | 6 | 1.38 | 6 | ( 1.1) | 6 | 1.28 |
| >=35 | 7 | ( 1.6) | 7 | 2.36 | 4 | ( 1.0) | 4 | 1.41 |
| Missing | 0 | | | | 0 | | | |
| Blood creatinine increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 4 | ( 0.7) | 4 | 1.00 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 4 | ( 0.9) | 4 | 1.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Alanine aminotransferase increased | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| SARS-CoV-2 test positive | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 1.23 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.43 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 3 | ( 0.7) | 3 | 1.01 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Blood immunoglobulin E increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.30 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Aspartate aminotransferase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood cholesterol increased | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood creatine phosphokinase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Glycosylated haemoglobin increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 1 | ( 0.2) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| International normalised ratio decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| International normalised ratio increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.33 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Transferrin saturation decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Weight decreased | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.66 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Catheterisation cardiac | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood pressure increased | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 0.71 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram ST segment abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatic specific antigen increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| QRS axis abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Amylase increased | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Antinuclear antibody positive | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Arthroscopy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood alkaline phosphatase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.61 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood creatine increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood glucose decreased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood glucose fluctuation | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood glucose increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Blood potassium increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood pressure decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood triglycerides increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.69 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood urine present | | | | | | | | |
| <25 | 1 | ( 0.3) | 3 | 0.98 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Body temperature increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bone density decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breath sounds abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Carbohydrate antigen 19-9 increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac murmur | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac stress test abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ejection fraction decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram P wave biphasic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram repolarisation abnormality | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram ST segment depression | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Electrocardiogram T wave inversion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eosinophil count increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Free fatty acids increased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Glomerular filtration rate decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Grip strength decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haematocrit increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemoglobin decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemoglobin increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic enzyme increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| International normalised ratio abnormal | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Intraocular pressure increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipase increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipids increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Liver function test abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 2 | 0.51 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Liver function test increased | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Low density lipoprotein increased | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Monocyte count decreased | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Monofilament pressure perception test | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Occult blood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Platelet count decreased | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.6) | 2 | 1.11 |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Red blood cell count decreased | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thyroid function test abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Transaminases increased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Vitamin D decreased | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Psychiatric disorders | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| All | | | | | | | | |
| <25 | 7 | ( 2.4) | 9 | 4.11 | 5 | ( 1.7) | 5 | 2.41 |
| >=25 - <30 | 18 | ( 2.9) | 19 | 3.38 | 10 | ( 1.6) | 12 | 2.38 |
| >=30 - <35 | 4 | ( 0.7) | 4 | 0.86 | 15 | ( 2.8) | 15 | 4.14 |
| >=35 | 7 | ( 1.6) | 8 | 2.46 | 7 | ( 1.6) | 7 | 1.85 |
| Missing | 0 | | | | 0 | | | |
| Insomnia | | | | | | | | |
| <25 | 3 | ( 1.0) | 3 | 1.26 | 0 | | | |
| >=25 - <30 | 5 | ( 0.8) | 5 | 0.94 | 4 | ( 0.6) | 5 | 1.10 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.4) | 2 | 0.74 | 2 | ( 0.4) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Anxiety | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 4 | ( 0.7) | 4 | 0.78 | 3 | ( 0.5) | 3 | 0.46 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Sleep disorder | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.7) | 2 | 1.16 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.46 | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Depression | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.92 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.33 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 6 | ( 1.1) | 6 | 1.66 |
| >=35 | 2 | ( 0.5) | 2 | 0.48 | 3 | ( 0.7) | 3 | 0.70 |
| Missing | 0 | | | | 0 | | | |
| Adjustment disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adjustment disorder with mixed anxiety and depressed mood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Disorientation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Listless | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Stress | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adjustment disorder with depressed mood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Affect lability | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Agitation | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anxiety disorder | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bruxism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Depressed mood | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Drug abuse | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Drug dependence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Emotional distress | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Fear | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Irritability | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.97 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Major depression | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mental status changes | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Mixed anxiety and depressive disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Mood swings | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nightmare | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Persistent depressive disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Phobia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Post-traumatic stress disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | | | | | | |
| All | | | | | | | | |
| <25 | 4 | ( 1.3) | 5 | 1.90 | 3 | ( 1.0) | 3 | 1.49 |
| >=25 - <30 | 16 | ( 2.6) | 19 | 4.10 | 10 | ( 1.6) | 18 | 3.28 |
| >=30 - <35 | 7 | ( 1.2) | 9 | 1.85 | 8 | ( 1.5) | 10 | 1.89 |
| >=35 | 4 | ( 1.0) | 6 | 1.60 | 6 | ( 1.5) | 9 | 3.34 |
| Missing | 0 | | | | 0 | | | |
| Colon adenoma | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.43 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gastric cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adenocarcinoma pancreas | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bladder papilloma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lung cancer metastatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Skin papilloma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Glioblastoma multiforme | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Haemangioma of liver | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Metastases to liver | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Oral fibroma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Salivary gland neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eye naevus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.36 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Osteoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Small cell lung cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bladder cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colorectal cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Acrochordon | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adenocarcinoma of colon | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Adrenal adenoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Basal cell carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Benign renal neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bowen's disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breast cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Breast cancer metastatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic myeloid leukaemia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colon cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colon cancer stage II | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysplastic naevus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Endometrial adenocarcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Gastrointestinal tract adenoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatocellular carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Invasive breast carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Invasive ductal breast carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Invasive lobular breast carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lipoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lung adenocarcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Lymphangioma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Malignant melanoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Malignant melanoma in situ | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Malignant peritoneal neoplasm | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metastases to bone marrow | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Metastases to lymph nodes | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Myxoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Neoplasm skin | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ovarian cancer metastatic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic carcinoma | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancreatic carcinoma metastatic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostate cancer | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatic adenoma | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal cell carcinoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal hamartoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Seborrhoeic keratosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 2 | 0.35 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Small intestine neuroendocrine tumour | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Squamous cell carcinoma of skin | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Uterine cancer | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Uterine leiomyoma | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Renal and urinary disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 6 | ( 2.1) | 10 | 4.73 | 7 | ( 2.4) | 7 | 3.30 |
| >=25 - <30 | 14 | ( 2.3) | 17 | 3.87 | 22 | ( 3.5) | 32 | 6.03 |
| >=30 - <35 | 19 | ( 3.4) | 22 | 5.21 | 15 | ( 2.9) | 16 | 3.32 |
| >=35 | 12 | ( 2.9) | 13 | 3.59 | 7 | ( 1.7) | 9 | 2.35 |
| Missing | 0 | | | | 0 | | | |
| Pollakiuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.73 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.61 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nephrolithiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.45 | 3 | ( 0.5) | 5 | 1.08 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ureterolithiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.43 | 2 | ( 0.3) | 2 | 0.31 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysuria | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.42 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 2 | 0.48 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Nephrotic syndrome | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal cyst | | | | | | | | |
| <25 | 3 | ( 1.1) | 3 | 1.88 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.35 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 2 | ( 0.5) | 2 | 0.71 |
| Missing | 0 | | | | 0 | | | |
| Renal failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal impairment | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 3 | ( 0.7) | 3 | 1.01 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chronic kidney disease | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.64 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Haematuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 2 | 0.54 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.39 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Acute kidney injury | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 3 | ( 0.5) | 3 | 0.46 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 2 | ( 0.5) | 2 | 0.60 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Bladder mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Bladder prolapse | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Calculus urinary | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Chromaturia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cystitis haemorrhagic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Diabetic nephropathy | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hydrocalyx | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Hydronephrosis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertonic bladder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Microalbuminuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Micturition urgency | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nephropathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nocturia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Polyuria | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Proteinuria | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pyelocaliectasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal colic | | | | | | | | |
| <25 | 0 | | | | 2 | ( 0.6) | 2 | 1.11 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Renal pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Strangury | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Stress urinary incontinence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urethral stenosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urinary incontinence | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Urinary retention | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.31 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urinary tract disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urinary tract inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Urinary tract obstruction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Urine odour abnormal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Reproductive system and breast disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 4 | ( 1.4) | 4 | 1.85 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 12 | ( 1.9) | 12 | 2.38 | 7 | ( 1.1) | 7 | 1.41 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.13 | 4 | ( 0.8) | 5 | 1.10 |
| >=35 | 8 | ( 2.0) | 8 | 2.26 | 11 | ( 2.7) | 14 | 3.73 |
| Missing | 0 | | | | 0 | | | |
| Benign prostatic hyperplasia | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.92 | 1 | ( 0.4) | 1 | 0.34 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.58 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Breast pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Menstruation delayed | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatic calcification | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Menopausal symptoms | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ovarian cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Uterine prolapse | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Erectile dysfunction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.47 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Menstruation irregular | | | | | | | | |
| <25 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pelvic discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrophic vulvovaginitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Breast mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cervical polyp | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Colpocele | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Dysmenorrhoea | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Ejaculation failure | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Galactorrhoea | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Genital prolapse | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Intermenstrual bleeding | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.4) | 2 | 0.72 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Menopausal disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Penile rash | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.39 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Prostatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.30 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pruritus genital | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Testicular cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Uterine enlargement | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Uterine polyp | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.51 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vaginal discharge | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Vaginal haemorrhage | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 2 | ( 0.5) | 2 | 0.47 |
| Missing | 0 | | | | 0 | | | |
| Vulvovaginal dryness | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vulvovaginal pruritus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Ear and labyrinth disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 4 | ( 1.4) | 7 | 2.87 | 2 | ( 0.7) | 2 | 0.97 |
| >=25 - <30 | 9 | ( 1.5) | 9 | 1.79 | 6 | ( 0.9) | 6 | 1.25 |
| >=30 - <35 | 9 | ( 1.6) | 9 | 1.74 | 9 | ( 1.7) | 9 | 2.35 |
| >=35 | 4 | ( 1.0) | 4 | 1.26 | 5 | ( 1.2) | 6 | 1.59 |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Vertigo | | | | | | | | |
| <25 | 3 | ( 1.0) | 4 | 1.62 | 2 | ( 0.7) | 2 | 0.97 |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.73 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 3 | ( 0.6) | 3 | 0.82 |
| >=35 | 2 | ( 0.5) | 2 | 0.65 | 2 | ( 0.4) | 3 | 0.68 |
| Missing | 0 | | | | 0 | | | |
| Ear pain | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.31 | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.31 | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.61 | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Ear inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eustachian tube dysfunction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cerumen impaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Deafness bilateral | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Deafness unilateral | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Ear discomfort | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| External ear pain | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypoacusis | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Meniere's disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Middle ear inflammation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Motion sickness | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Presbyacusis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tinnitus | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Vertigo positional | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.36 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Blood and lymphatic system disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 5 | ( 1.7) | 5 | 2.27 | 4 | ( 1.3) | 4 | 2.03 |
| >=25 - <30 | 7 | ( 1.1) | 7 | 1.59 | 10 | ( 1.6) | 10 | 1.98 |
| >=30 - <35 | 10 | ( 1.8) | 12 | 2.93 | 6 | ( 1.1) | 6 | 1.12 |
| >=35 | 11 | ( 2.7) | 11 | 3.27 | 10 | ( 2.4) | 10 | 3.02 |
| Missing | 0 | | | | 0 | | | |
| Anaemia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 2 | ( 0.7) | 2 | 0.93 |
| >=25 - <30 | 7 | ( 1.1) | 7 | 1.59 | 7 | ( 1.1) | 7 | 1.31 |
| >=30 - <35 | 4 | ( 0.7) | 6 | 1.55 | 0 | | | |
| >=35 | 7 | ( 1.7) | 7 | 2.12 | 5 | ( 1.2) | 5 | 1.64 |
| Missing | 0 | | | | 0 | | | |
| Blood loss anaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.37 |
| >=35 | 1 | ( 0.2) | 1 | 0.37 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Eosinophilia | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypochromic anaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Iron deficiency anaemia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Leukocytosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.36 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Leukopenia | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lymphadenopathy | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Lymphadenopathy mediastinal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Normocytic anaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Pancytopenia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Polycythaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Splenomegaly | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombocytopenia | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Thrombocytosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Hepatobiliary disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 5 | ( 1.7) | 6 | 2.88 | 2 | ( 0.6) | 4 | 2.19 |
| >=25 - <30 | 6 | ( 1.0) | 8 | 1.67 | 7 | ( 1.1) | 7 | 1.29 |
| >=30 - <35 | 6 | ( 1.1) | 8 | 1.73 | 8 | ( 1.5) | 10 | 2.27 |
| >=35 | 2 | ( 0.5) | 3 | 0.72 | 4 | ( 1.0) | 4 | 1.17 |
| Missing | 0 | | | | 0 | | | |
| Hepatic steatosis | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 4 | ( 0.7) | 4 | 0.78 | 4 | ( 0.6) | 4 | 0.83 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.53 | 3 | ( 0.6) | 3 | 0.55 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Alcoholic liver disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.28 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cholecystitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Cholelithiasis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gallbladder cholesterolosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Bile duct stone | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.36 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Biliary colic | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Biliary dyskinesia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.48 |
| Missing | 0 | | | | 0 | | | |
| Cholecystitis chronic | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Gallbladder polyp | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic cirrhosis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 2 | ( 0.4) | 2 | 0.52 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic cyst | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic function abnormal | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.64 | 1 | ( 0.3) | 1 | 0.55 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatic mass | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hepatomegaly | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperplastic cholecystopathy | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.65 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertransaminasaemia | | | | | | | | |
| <25 | 1 | ( 0.3) | 2 | 0.67 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Liver disorder | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Non-alcoholic steatohepatitis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Nonalcoholic fatty liver disease | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Steatohepatitis | | | | | | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Immune system disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 2 | ( 0.7) | 2 | 0.93 | 2 | ( 0.7) | 2 | 1.16 |
| >=25 - <30 | 4 | ( 0.6) | 5 | 0.90 | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 5 | ( 0.9) | 5 | 1.32 | 7 | ( 1.3) | 8 | 2.20 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 4 | ( 0.9) | 4 | 1.13 |
| Missing | 0 | | | | 0 | | | |
| Seasonal allergy | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 3 | ( 0.5) | 3 | 0.58 | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 3 | ( 0.5) | 3 | 0.66 | 5 | ( 0.9) | 5 | 1.48 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 2 | ( 0.4) | 2 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Allergy to arthropod bite | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.56 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.16 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.45 |
| Missing | 0 | | | | 0 | | | |
| Food allergy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Allergy to arthropod sting | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.1) | 1 | 0.25 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Anaphylactic reaction | | | | | | | | |
| <25 | 1 | ( 0.4) | 1 | 0.59 | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Drug hypersensitivity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypersensitivity | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Immunisation reaction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 2 | 0.39 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Congenital, familial and genetic disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 2 | ( 0.3) | 2 | 0.57 | 3 | ( 0.5) | 3 | 0.56 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.51 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 2 | ( 0.5) | 2 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Cystic fibrosis lung | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Type V hyperlipidaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.29 | 1 | ( 0.1) | 1 | 0.26 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.18 | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.36 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Atrial septal defect | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Congenital syphilitic osteochondritis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Corneal dystrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hydrocele | | | | | | | | |
| <25 | 1 | ( 0.3) | 1 | 0.33 | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypertrophic cardiomyopathy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Myotonic dystrophy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Endocrine disorders | | | | | | | | |
| All | | | | | | | | |
| <25 | 0 | | | | 3 | ( 1.0) | 3 | 1.57 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 8 | ( 1.3) | 8 | 1.46 |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 5 | ( 1.0) | 5 | 1.08 |
| >=35 | 4 | ( 1.0) | 4 | 1.02 | 2 | ( 0.5) | 2 | 0.69 |
| Missing | 0 | | | | 0 | | | |
| Hypothyroidism | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Adrenal mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Adrenocortical insufficiency acute | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.3) | 1 | 0.60 |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.28 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Autoimmune thyroiditis | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.2) | 1 | 0.24 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Goitre | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperplasia adrenal | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperprolactinaemia | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hyperthyroidism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.16 |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Hypogonadism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 1 | ( 0.2) | 1 | 0.18 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Inappropriate antidiuretic hormone secretion | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Missing | 0 | | | | 0 | | | |
| Secondary hypogonadism | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.3) | 1 | 0.46 |
| Missing | 0 | | | | 0 | | | |
| Thyroid mass | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 2 | ( 0.3) | 2 | 0.41 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 2 | ( 0.5) | 2 | 0.54 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Surgical and medical procedures | | | | | | | | |
| All | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 2 | ( 0.4) | 2 | 0.67 | 3 | ( 0.6) | 3 | 0.84 |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Cardiac pacemaker replacement | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 1 | ( 0.2) | 1 | 0.15 | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.31 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Knee operation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 1 | ( 0.3) | 1 | 0.27 | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Large intestinal polypectomy | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.20 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Removal of foreign body | | | | | | | | |
| <25 | 0 | | | | 1 | ( 0.4) | 1 | 0.37 |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Adverse events by baseline BMI group, system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

| | Insulin icodec | | | | Daily basal insulin | | | |
|---|---|---|---|---|---|---|---|---|
| | N | (Adj.%) | E | Adj.R | N | (Adj.%) | E | Adj.R |
| Shoulder operation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Skin neoplasm excision | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 1 | ( 0.2) | 1 | 0.15 |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Spinal operation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 0 | | | |
| >=35 | 0 | | | | 1 | ( 0.2) | 1 | 0.23 |
| Missing | 0 | | | | 0 | | | |
| Toe amputation | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Tooth extraction | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 1 | ( 0.2) | 1 | 0.33 | 0 | | | |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Social circumstances | | | | | | | | |
| All | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |
| Menopause | | | | | | | | |
| <25 | 0 | | | | 0 | | | |
| >=25 - <30 | 0 | | | | 0 | | | |
| >=30 - <35 | 0 | | | | 1 | ( 0.2) | 1 | 0.33 |
| >=35 | 0 | | | | 0 | | | |
| Missing | 0 | | | | 0 | | | |

%: Percentage of subjects with one or more events, BMI: Body mass index (kg/m^2), E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.