インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
1. 曝露状況及びベースライン特性

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7.1 Exposure to the drug and baseline characteristics

7.1.1 Exposure by pool and trial - summary - safety analysis set

	Insulin icodec		Daily basal insulin		Total	
	N	(PYE)	N	(PYE)	N	(PYE)
Phase 3a pool	2170	(1681.23)	2170	(1680.58)	4340	(3361.81)
T2D pool	1880	(1538.92)	1878	(1536.46)	3758	(3075.38)
ONWARDS 1	492	(485.88)	492	(485.03)	984	(970.91)
ONWARDS 2	262	(155.25)	263	(152.77)	525	(308.02)
ONWARDS 3	293	(170.90)	294	(171.13)	587	(342.03)
ONWARDS 4	291	(167.36)	291	(166.80)	582	(334.16)
ONWARDS 5	542	(559.54)	538	(560.72)	1080	(1120.26)
ONWARDS 6	290	(142.31)	292	(144.12)	582	(286.43)

N: Number of subjects, PYE: Patient years of exposure (1 PYE = 365.25 days), T2D: Type 2 diabetes. Daily basal insulin: IDeg (ONWARDS 2, ONWARDS 3, ONWARDS 6), IGlar U100 (ONWARDS 1, ONWARDS 4), and once-daily analogues (IDeg, IGlar U100, IGlar U300) (ONWARDS 5). Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1.

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7.1.2 Exposure by month - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	2170		2170		4340	
Duration of exposure						
>= 1 month	2156	(99.3)	2157	(99.4)	4313	(99.4)
>= 2 months	2146	(98.9)	2132	(98.2)	4278	(98.6)
>= 3 months	2135	(98.4)	2122	(97.8)	4257	(98.1)
>= 4 months	2118	(97.6)	2113	(97.4)	4231	(97.5)
>= 5 months	2105	(97.0)	2102	(96.9)	4207	(96.9)
>= 6 months	2038	(93.9)	2037	(93.9)	4075	(93.9)
>= 7 months	1779	(82.0)	1777	(81.9)	3556	(81.9)
>= 8 months	985	(45.4)	993	(45.8)	1978	(45.6)
>= 9 months	981	(45.2)	987	(45.5)	1968	(45.4)
>= 10 months	974	(44.9)	986	(45.4)	1960	(45.2)
>= 11 months	972	(44.8)	982	(45.2)	1954	(45.0)
>= 12 months	614	(28.3)	643	(29.6)	1257	(29.0)

%: Percentage of subjects, N: Number of subjects. 1 month = 30.5 days. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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7.1.3 Exposure by month - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	1880		1878		3758	
Duration of exposure						
>= 1 month	1868	(99.4)	1866	(99.4)	3734	(99.4)
>= 2 months	1859	(98.9)	1845	(98.2)	3704	(98.6)
>= 3 months	1851	(98.5)	1835	(97.7)	3686	(98.1)
>= 4 months	1837	(97.7)	1828	(97.3)	3665	(97.5)
>= 5 months	1828	(97.2)	1818	(96.8)	3646	(97.0)
>= 6 months	1811	(96.3)	1809	(96.3)	3620	(96.3)
>= 7 months	1779	(94.6)	1777	(94.6)	3556	(94.6)
>= 8 months	985	(52.4)	993	(52.9)	1978	(52.6)
>= 9 months	981	(52.2)	987	(52.6)	1968	(52.4)
>= 10 months	974	(51.8)	986	(52.5)	1960	(52.2)
>= 11 months	972	(51.7)	982	(52.3)	1954	(52.0)
>= 12 months	614	(32.7)	643	(34.2)	1257	(33.5)

%: Percentage of subjects, N: Number of subjects, 1 month = 30.5 days. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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7.1.4 Exposure by demographics - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(PYE)	N	(PYE)	N	(PYE)
Number of subjects	2170	(1681.23)	2170	(1680.58)	4340	(3361.81)
Sex						
Male	1268	(983.62)	1219	(942.57)	2487	(1926.19)
Female	902	(697.61)	951	(738.01)	1853	(1435.62)
Age group						
>=18 - <65 years	1501	(1146.36)	1498	(1152.98)	2999	(2299.34)
>=65 - <75 years	569	(452.73)	592	(462.37)	1161	(915.10)
>=65 years	669	(534.87)	672	(527.60)	1341	(1062.47)
>=75 years	100	(82.14)	80	(65.23)	180	(147.37)
Race						
White	1563	(1242.90)	1522	(1219.98)	3085	(2462.88)
Black or African American	76	(56.42)	73	(59.43)	149	(115.85)
Asian	469	(331.92)	524	(364.20)	993	(696.12)
Other	47	(40.57)	34	(26.92)	81	(67.49)
Missing	15	(9.42)	17	(10.06)	32	(19.47)
Ethnicity						
Not Hispanic or Latino	1898	(1481.32)	1889	(1475.30)	3787	(2956.62)
Hispanic or Latino	257	(191.00)	264	(195.23)	521	(386.22)
Missing	15	(8.92)	17	(10.06)	32	(18.97)
Region						
Europe	918	(760.68)	894	(732.19)	1812	(1492.88)
North America	697	(545.23)	661	(535.57)	1358	(1080.80)
South America	128	(82.20)	131	(85.02)	259	(167.21)
Africa	25	(15.03)	25	(14.82)	50	(29.85)
Asia	402	(278.09)	459	(312.98)	861	(591.07)

N: Number of subjects, PYE: Patient years of exposure (1 PYE = 365.25 days). Other race includes American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander. Subjects from France did not report race and ethnicity. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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7.1.5 Exposure by demographics - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(PYE)	N	(PYE)	N	(PYE)
Number of subjects	1880	(1538.92)	1878	(1536.46)	3758	(3075.38)
Sex						
Male	1103	(902.68)	1047	(857.48)	2150	(1760.16)
Female	777	(636.24)	831	(678.98)	1608	(1315.22)
Age group						
>=18 - <65 years	1234	(1015.10)	1227	(1019.39)	2461	(2034.49)
>=65 - <75 years	549	(443.15)	574	(453.36)	1123	(896.50)
>=65 years	646	(523.83)	651	(517.07)	1297	(1040.90)
>=75 years	97	(80.68)	77	(63.71)	174	(144.39)
Race						
White	1333	(1130.55)	1304	(1112.99)	2637	(2243.54)
Black or African American	67	(52.07)	71	(58.43)	138	(110.50)
Asian	418	(306.31)	452	(328.07)	870	(634.38)
Other	47	(40.57)	34	(26.92)	81	(67.49)
Missing	15	(9.42)	17	(10.06)	32	(19.47)
Ethnicity						
Not Hispanic or Latino	1618	(1344.03)	1607	(1336.23)	3225	(2680.26)
Hispanic or Latino	247	(185.98)	254	(190.17)	501	(376.15)
Missing	15	(8.92)	17	(10.06)	32	(18.97)
Region						
Europe	782	(693.26)	755	(663.77)	1537	(1357.03)
North America	591	(494.44)	576	(493.99)	1167	(988.42)
South America	128	(82.20)	131	(85.02)	259	(167.21)
Africa	25	(15.03)	25	(14.82)	50	(29.85)
Asia	354	(254.00)	391	(278.87)	745	(532.87)

N: Number of subjects, PYE: Patient years of exposure (1 PYE = 365.25 days), Other race includes American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander. Subjects from France did not report race and ethnicity. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.6 Exposure by baseline characteristics - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(PYE)	N	(PYE)	N	(PYE)
Number of subjects	2170	(1681.23)	2170	(1680.58)	4340	(3361.81)
HbA1c						
<8% (<64 mmol/mol)	888	(649.98)	897	(659.50)	1785	(1309.48)
>=8% (>=64 mmol/mol)	1282	(1031.26)	1272	(1020.75)	2554	(2052.01)
Missing	0		1	(0.33)	1	(0.33)
Duration of diabetes						
<10 years	764	(626.99)	796	(656.89)	1560	(1283.88)
>=10 years	1406	(1054.24)	1374	(1023.69)	2780	(2077.93)
BMI (kg/m^2)						
<25	394	(277.49)	429	(292.08)	823	(569.57)
>=25 - <30	736	(560.40)	747	(567.52)	1483	(1127.92)
>=30 - <35	600	(478.51)	572	(458.12)	1172	(936.63)
>=35	440	(364.84)	421	(361.74)	861	(726.58)
Missing	0		1	(1.11)	1	(1.11)
Renal function (eGFR, mL/min/1.73m^2)						
Normal (>=90)	1121	(868.19)	1137	(876.95)	2258	(1745.14)
Mild impairment (>=60 - <90)	837	(649.05)	791	(615.74)	1628	(1264.79)
Moderate impairment (>=30 - <60)	206	(158.35)	237	(183.27)	443	(341.63)
Severe impairment (<30)	5	(5.06)	4	(4.29)	9	(9.35)
Missing	1	(0.58)	1	(0.33)	2	(0.90)
Pre-trial insulin treatment						
Insulin naive	1327	(1216.31)	1324	(1216.89)	2651	(2433.20)
Basal insulin	262	(155.25)	263	(152.77)	525	(308.02)
Basal-bolus insulin regimen	581	(309.67)	583	(310.92)	1164	(620.59)
Hepatic function						
Normal	2080	(1612.64)	2071	(1603.16)	4151	(3215.80)
Impaired	8	(6.17)	7	(5.74)	15	(11.91)
Missing	82	(62.42)	92	(71.68)	174	(134.10)
COVID-19 trial co-participation						
Yes	0		0		0	
No	2170	(1681.23)	2170	(1680.58)	4340	(3361.81)

BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, PYE: Patient years of exposure (1 PYE = 365.25 days). Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. COVID-19 trial includes clinical trials with the primary objective of investigating COVID-19 vaccination, treatment and COVID-19 postinfectious conditions of an approved or non-approved investigational medicinal product. Baseline refers to week 0 except for renal function and hepatic function, these are evaluated at screening, and for COVID-19 trial co-participation, which is evaluated as anytime during the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.1.7 Exposure by baseline characteristics - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(PYE)	N	(PYE)	N	(PYE)
Number of subjects	1880	(1538.92)	1878	(1536.46)	3758	(3075.38)
HbA1c						
<8% (<64 mmol/mol)	699	(557.73)	708	(565.93)	1407	(1123.66)
>=8% (>=64 mmol/mol)	1181	(981.19)	1169	(970.20)	2350	(1951.40)
Missing	0		1	(0.33)	1	(0.33)
Duration of diabetes						
<10 years	689	(589.76)	714	(616.53)	1403	(1206.29)
>=10 years	1191	(949.16)	1164	(919.93)	2355	(1869.09)
BMI (kg/m^2)						
<25	289	(226.72)	294	(224.63)	583	(451.35)
>=25 - <30	618	(502.36)	645	(517.80)	1263	(1020.16)
>=30 - <35	554	(455.36)	531	(438.19)	1085	(893.56)
>=35	419	(354.48)	407	(354.73)	826	(709.21)
Missing	0		1	(1.11)	1	(1.11)
Renal function (eGFR, mL/min/1.73m^2)						
Normal (>=90)	924	(770.83)	947	(783.47)	1871	(1554.30)
Mild impairment (>=60 - <90)	749	(606.63)	698	(569.62)	1447	(1176.25)
Moderate impairment (>=30 - <60)	201	(155.82)	228	(178.77)	429	(334.58)
Severe impairment (<30)	5	(5.06)	4	(4.29)	9	(9.35)
Missing	1	(0.58)	1	(0.33)	2	(0.90)
Pre-trial insulin treatment						
Insulin naive	1327	(1216.31)	1324	(1216.89)	2651	(2433.20)
Basal insulin	262	(155.25)	263	(152.77)	525	(308.02)
Basal-bolus insulin regimen	291	(167.36)	291	(166.80)	582	(334.16)
Hepatic function						
Normal	1799	(1474.84)	1786	(1462.55)	3585	(2937.40)
Impaired	7	(5.67)	7	(5.74)	14	(11.41)
Missing	74	(58.41)	85	(68.17)	159	(126.58)
COVID-19 trial co-participation						
Yes	0		0		0	
No	1880	(1538.92)	1878	(1536.46)	3758	(3075.38)

BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, PYE: Patient years of exposure (1 PYE = 365.25 days), Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. COVID-19 trial includes clinical trials with the primary objective of investigating COVID-19 vaccination, treatment and COVID-19 postinfectious conditions of an approved or non-approved investigational medicinal product. Baseline refers to week 0 except for renal function and hepatic function, these are evaluated at screening, and for COVID-19 trial co-participation, which is evaluated as anytime during 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.

7.1.8 Subject disposition - summary - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Randomised	2172	(100.0)	2175	(100.0)	4347	(100.0)
Exposed	2170	(99.9)	2170	(99.8)	4340	(99.8)
Full analysis set (FAS)	2172	(100.0)	2175	(100.0)	4347	(100.0)
Safety analysis set (SAS)	2170	(99.9)	2170	(99.8)	4340	(99.8)
Permanent discontinuation of trial product	131	(6.0)	114	(5.2)	245	(5.6)
Adverse event	30	(1.4)	24	(1.1)	54	(1.2)
Hypoglycaemic episode	4	(0.2)	1	(0.0)	5	(0.1)
Protocol deviation	4	(0.2)	3	(0.1)	7	(0.2)
Lack of efficacy	1	(0.0)	0		1	(0.0)
Switch to another basal insulin analogue	0		0		0	
Intensification to a basal bolus regime or continuous use of bolus insulin	2	(0.1)	0		2	(0.0)
Lost to follow-up	14	(0.6)	22	(1.0)	36	(0.8)
Pregnancy	3	(0.1)	0		3	(0.1)
Site closure	1	(0.0)	0		1	(0.0)
Epi/pandemic	0		0		0	
Withdrawal of consent	34	(1.6)	38	(1.7)	72	(1.7)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	38	(1.7)	26	(1.2)	64	(1.5)
Withdrawn from trial	91	(4.2)	96	(4.4)	187	(4.3)
Withdrawal of consent by subject	49	(2.3)	49	(2.3)	98	(2.3)
Lost to follow-up	20	(0.9)	27	(1.2)	47	(1.1)
Investigator decision	8	(0.4)	8	(0.4)	16	(0.4)
Death	12	(0.6)	12	(0.6)	24	(0.6)
Site closure	2	(0.1)	0		2	(0.0)
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	2081	(95.8)	2083	(95.8)	4164	(95.8)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	2041	(94.0)	2060	(94.7)	4101	(94.3)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	40	(1.8)	23	(1.1)	63	(1.4)

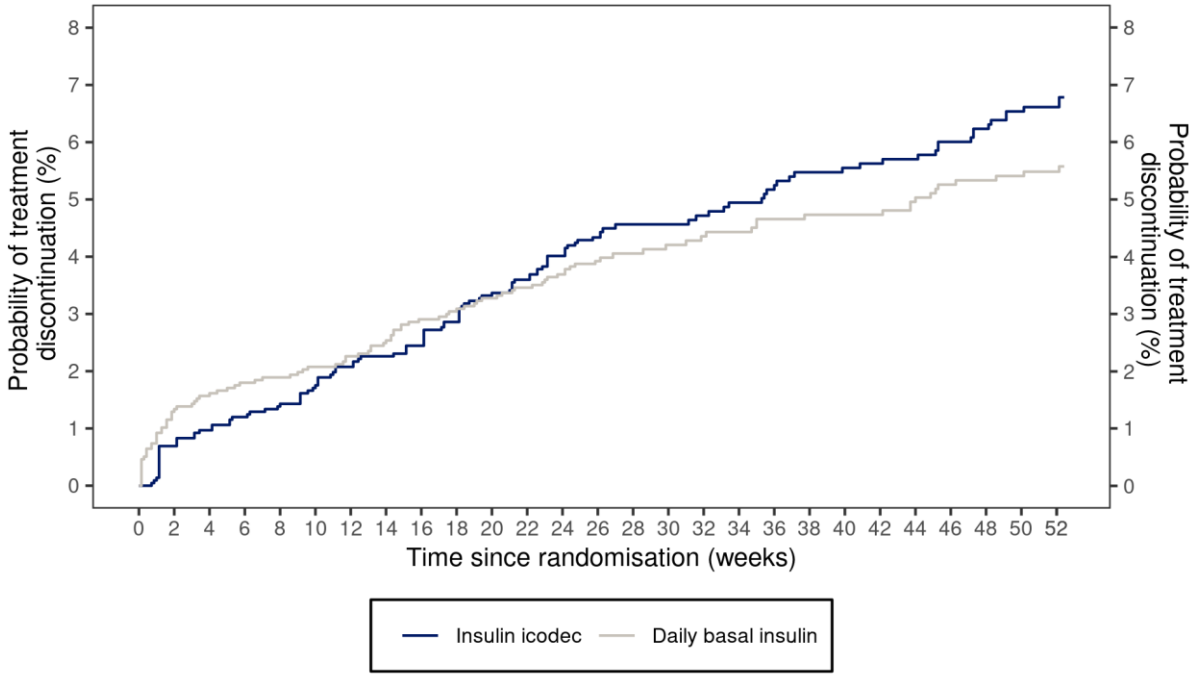
%: Percentage of subjects, N: Number of subjects. Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4 and 6 (main part), and to week 52 visit for ONWARDS 1 (main part) and 5. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.1.9 Subject disposition - summary - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Randomised	1882	(100.0)	1883	(100.0)	3765	(100.0)
Exposed	1880	(99.9)	1878	(99.7)	3758	(99.8)
Full analysis set (FAS)	1882	(100.0)	1883	(100.0)	3765	(100.0)
Safety analysis set (SAS)	1880	(99.9)	1878	(99.7)	3758	(99.8)
Permanent discontinuation of trial product	113	(6.0)	105	(5.6)	218	(5.8)
Adverse event	29	(1.5)	23	(1.2)	52	(1.4)
Hypoglycaemic episode	3	(0.2)	1	(0.1)	4	(0.1)
Protocol deviation	3	(0.2)	3	(0.2)	6	(0.2)
Lack of efficacy	1	(0.1)	0		1	(0.0)
Switch to another basal insulin analogue	0		0		0	
Intensification to a basal bolus regime or continuous use of bolus insulin	2	(0.1)	0		2	(0.1)
Lost to follow-up	14	(0.7)	21	(1.1)	35	(0.9)
Pregnancy	1	(0.1)	0		1	(0.0)
Site closure	1	(0.1)	0		1	(0.0)
Epi/pandemic	0		0		0	
Withdrawal of consent	30	(1.6)	35	(1.9)	65	(1.7)
Safety concern related to trial product or unacceptable intolerability	0		0		0	
Other	29	(1.5)	22	(1.2)	51	(1.4)
Withdrawn from trial	80	(4.3)	88	(4.7)	168	(4.5)
Withdrawal of consent by subject	40	(2.1)	42	(2.2)	82	(2.2)
Lost to follow-up	19	(1.0)	26	(1.4)	45	(1.2)
Investigator decision	8	(0.4)	8	(0.4)	16	(0.4)
Death	11	(0.6)	12	(0.6)	23	(0.6)
Site closure	2	(0.1)	0		2	(0.1)
Epi/pandemic	0		0		0	
Completed scheduled end-of-treatment visit	1804	(95.9)	1798	(95.5)	3602	(95.7)
Completed scheduled end-of-treatment visit without permanent discontinuation of trial product	1769	(94.0)	1777	(94.4)	3546	(94.2)
Completed scheduled end-of-treatment visit after permanent discontinuation of trial product	35	(1.9)	21	(1.1)	56	(1.5)

%: Percentage of subjects, N: Number of subjects, Lack of efficacy criterion applies to all trials except ONWARDS 5, while both switch to another basal insulin analogue and intensification to a basal bolus regime or continuous use of bolus insulin only apply to ONWARDS 5. Scheduled end-of-treatment visit refers to week 26 visit for ONWARDS 2-4, and to week 52 visit for ONWARDS 1 (main part) and 5. T2D pool. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.10 Time to permanent discontinuation of trial product - cumulative incidence plot - safety analysis set - phase 3a pool

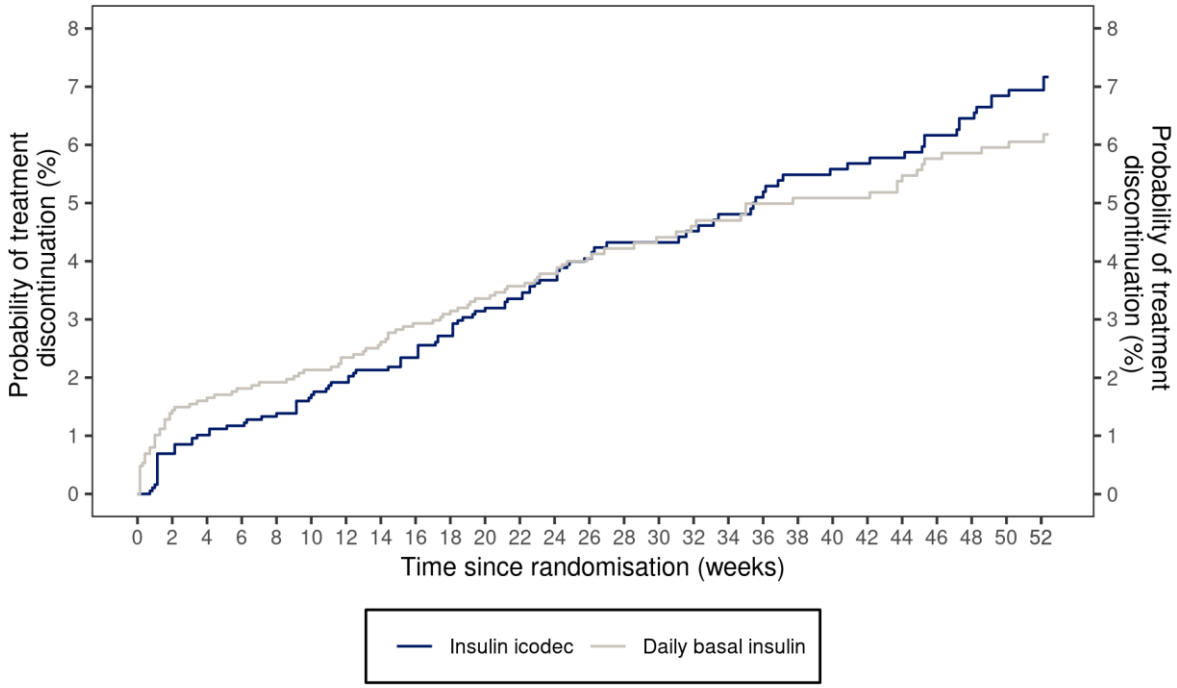


Safety analysis set. Observed data. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): TR01DURW EOTSTT; criteria: POOLGR2 == "Phase 3a pool" & SAFFL == "Y" & !is.na(TR01DURW)

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:56:28 - fslkmsas/fsldiscontkmp3asas.png

7.1.11 Time to permanent discontinuation of trial product - cumulative incidence plot - safety analysis set - T2D pool

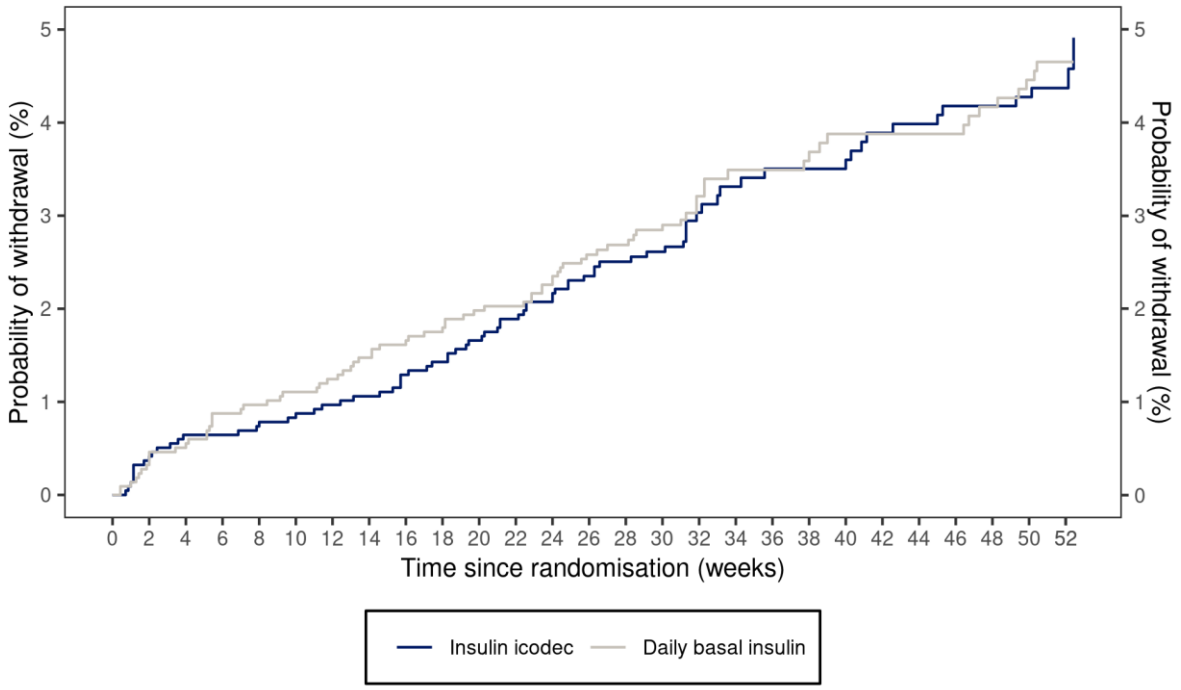


Safety analysis set. Observed data. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): TR01DURW EOTSTT; criteria: POOLGR1 == "T2D pool" & SAFFL == "Y" & !is.na(TR01DURW)

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:56:30 - fslkmsas/fsldiscontkmt2dsas.png

7.1.12 Time to withdrawal from trial - cumulative incidence plot - safety analysis set - phase 3a pool

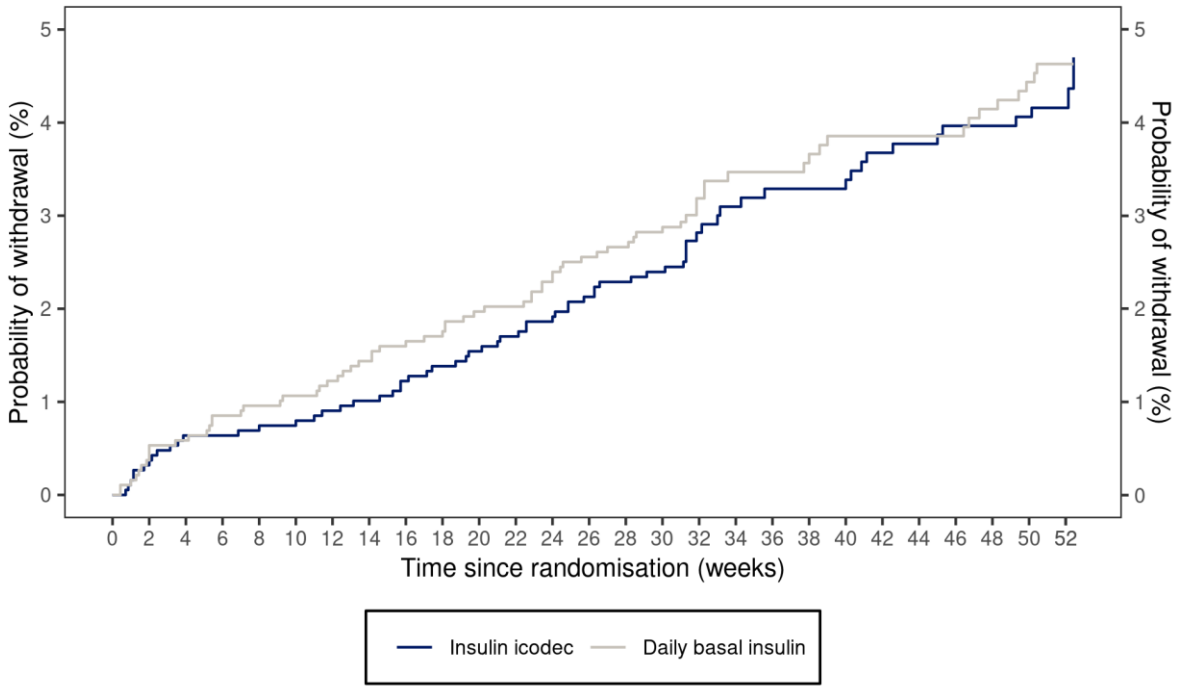


Safety analysis set. Observed data. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adsl.xpt; variable(s): INTRDURW EOSSTT; criteria: POOLGR2 == "Phase 3a pool" & SAFFL == "Y" & !is.na(INTRDURW)

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:56:32 - fslkmsas/fslwithdrawnkmp3asas.png

7.1.13 Time to withdrawal from trial - cumulative incidence plot - safety analysis set - T2D pool



Safety analysis set. Observed data. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): INTRDURW EOSSTT; criteria: POOLGR1 == "T2D pool" & SAFFL == "Y" & !is.na(INTRDURW)

nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:56:35 - fslkmsas/fslwithdrawnkmt2dsas.png

7.1.14 Demographics - summary - safety analysis set - phase 3a pool

	Insulin icodec	Daily basal insulin	Total
Number of subjects	2170	2170	4340
Sex, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Male	1268 (58.4)	1219 (56.2)	2487 (57.3)
Female	902 (41.6)	951 (43.8)	1853 (42.7)
Age (years)			
N	2170	2170	4340
Mean (SD)	57.4 (12.1)	57.6 (11.7)	57.5 (11.9)
Median	59.0	59.0	59.0
Min ; Max	18.0 ; 94.0	18.0 ; 84.0	18.0 ; 94.0
Age group, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
>=18 - <65 years	1501 (69.2)	1498 (69.0)	2999 (69.1)
>=65 - <75 years	569 (26.2)	592 (27.3)	1161 (26.8)
>=65 years	669 (30.8)	672 (31.0)	1341 (30.9)
>=75 years	100 (4.6)	80 (3.7)	180 (4.1)
Race, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
White	1563 (72.0)	1522 (70.1)	3085 (71.1)
Black or African American	76 (3.5)	73 (3.4)	149 (3.4)
Asian	469 (21.6)	524 (24.1)	993 (22.9)
Other	47 (2.2)	34 (1.6)	81 (1.9)
Missing	15 (0.7)	17 (0.8)	32 (0.7)
Ethnicity, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Not Hispanic or Latino	1898 (87.5)	1889 (87.1)	3787 (87.3)
Hispanic or Latino	257 (11.8)	264 (12.2)	521 (12.0)
Missing	15 (0.7)	17 (0.8)	32 (0.7)
Region, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Europe	918 (42.3)	894 (41.2)	1812 (41.8)
North America	697 (32.1)	661 (30.5)	1358 (31.3)
South America	128 (5.9)	131 (6.0)	259 (6.0)
Africa	25 (1.2)	25 (1.2)	50 (1.2)
Asia	402 (18.5)	459 (21.2)	861 (19.8)

%: Percentage of subjects, N: Number of subjects, SD: Standard deviation. Other race includes American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander. Subjects from France did not report race and ethnicity. 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): SEX AGEGR1 AGEGR2 RACE RACE2 ETHNIC REGION1 COUNTRY2 AAGE; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"

Demographics - summary - safety analysis set - phase 3a pool

	Insulin icodec	Daily basal insulin	Total
Country/area of residence, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Argentina	27 (1.2)	28 (1.3)	55 (1.3)
Austria	24 (1.1)	19 (0.9)	43 (1.0)
Belgium	7 (0.3)	11 (0.5)	18 (0.4)
Brazil	27 (1.2)	24 (1.1)	51 (1.2)
Bulgaria	19 (0.9)	14 (0.6)	33 (0.8)
Canada	142 (6.5)	120 (5.5)	262 (6.0)
China	49 (2.3)	51 (2.4)	100 (2.3)
Croatia	22 (1.0)	14 (0.6)	36 (0.8)
Czech Republic	25 (1.2)	26 (1.2)	51 (1.2)
Denmark	17 (0.8)	15 (0.7)	32 (0.7)
France	14 (0.6)	16 (0.7)	30 (0.7)
Germany	94 (4.3)	98 (4.5)	192 (4.4)
Greece	72 (3.3)	62 (2.9)	134 (3.1)
Hungary	67 (3.1)	75 (3.5)	142 (3.3)
India	102 (4.7)	115 (5.3)	217 (5.0)
Israel	20 (0.9)	17 (0.8)	37 (0.9)
Italy	61 (2.8)	60 (2.8)	121 (2.8)
Japan	205 (9.4)	224 (10.3)	429 (9.9)
Korea	23 (1.1)	47 (2.2)	70 (1.6)
Mexico	74 (3.4)	79 (3.6)	153 (3.5)
Netherlands	11 (0.5)	9 (0.4)	20 (0.5)
Poland	112 (5.2)	101 (4.7)	213 (4.9)
Portugal	15 (0.7)	13 (0.6)	28 (0.6)
Romania	22 (1.0)	17 (0.8)	39 (0.9)
Russia	126 (5.8)	153 (7.1)	279 (6.4)
Slovakia	30 (1.4)	33 (1.5)	63 (1.5)
South Africa	25 (1.2)	25 (1.2)	50 (1.2)
Spain	36 (1.7)	29 (1.3)	65 (1.5)
Taiwan	23 (1.1)	22 (1.0)	45 (1.0)
Turkey	58 (2.7)	55 (2.5)	113 (2.6)
Ukraine	18 (0.8)	12 (0.6)	30 (0.7)
United Kingdom	48 (2.2)	45 (2.1)	93 (2.1)
United States	555 (25.6)	541 (24.9)	1096 (25.3)

%: Percentage of subjects, N: Number of subjects, SD: Standard deviation. Other race includes American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander. Subjects from France did not report race and ethnicity. 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): SEX AGEGR1 AGEGR2 RACE RACE2 ETHNIC REGION1 COUNTRY2 AAGE; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"
nn1436/nn1436-iss/submission_20221024_er
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7.1.15 Demographics - summary - safety analysis set - T2D pool

	Insulin icodec	Daily basal insulin	Total
Number of subjects	1880	1878	3758
Sex, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Male	1103 (58.7)	1047 (55.8)	2150 (57.2)
Female	777 (41.3)	831 (44.2)	1608 (42.8)
Age (years)			
N	1880	1878	3758
Mean (SD)	59.4 (10.3)	59.6 (9.8)	59.5 (10.1)
Median	60.0	60.0	60.0
Min ; Max	19.0 ; 94.0	21.0 ; 84.0	19.0 ; 94.0
Age group, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
>=18 - <65 years	1234 (65.6)	1227 (65.3)	2461 (65.5)
>=65 - <75 years	549 (29.2)	574 (30.6)	1123 (29.9)
>=65 years	646 (34.4)	651 (34.7)	1297 (34.5)
>=75 years	97 (5.2)	77 (4.1)	174 (4.6)
Race, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
White	1333 (70.9)	1304 (69.4)	2637 (70.2)
Black or African American	67 (3.6)	71 (3.8)	138 (3.7)
Asian	418 (22.2)	452 (24.1)	870 (23.2)
Other	47 (2.5)	34 (1.8)	81 (2.2)
Missing	15 (0.8)	17 (0.9)	32 (0.9)
Ethnicity, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Not Hispanic or Latino	1618 (86.1)	1607 (85.6)	3225 (85.8)
Hispanic or Latino	247 (13.1)	254 (13.5)	501 (13.3)
Missing	15 (0.8)	17 (0.9)	32 (0.9)
Region, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Europe	782 (41.6)	755 (40.2)	1537 (40.9)
North America	591 (31.4)	576 (30.7)	1167 (31.1)
South America	128 (6.8)	131 (7.0)	259 (6.9)
Africa	25 (1.3)	25 (1.3)	50 (1.3)
Asia	354 (18.8)	391 (20.8)	745 (19.8)

%: Percentage of subjects, N: Number of subjects, SD: Standard deviation, Other race includes American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander. Subjects from France did not report race and ethnicity. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): SEX AGEGR1 AGEGR2 RACE RACE2 ETHNIC REGION1 COUNTRY2 AAGE; criteria: SAFFL == "Y" & POOLGR1 == "T2D pool"

Demographics - summary - safety analysis set - T2D pool

	Insulin icodec	Daily basal insulin	Total
Country/area of residence, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Argentina	27 (1.4)	28 (1.5)	55 (1.5)
Austria	14 (0.7)	14 (0.7)	28 (0.7)
Belgium	7 (0.4)	11 (0.6)	18 (0.5)
Brazil	27 (1.4)	24 (1.3)	51 (1.4)
Bulgaria	19 (1.0)	14 (0.7)	33 (0.9)
Canada	121 (6.4)	112 (6.0)	233 (6.2)
China	49 (2.6)	51 (2.7)	100 (2.7)
Croatia	22 (1.2)	14 (0.7)	36 (1.0)
Czech Republic	25 (1.3)	26 (1.4)	51 (1.4)
Denmark	17 (0.9)	15 (0.8)	32 (0.9)
France	14 (0.7)	16 (0.9)	30 (0.8)
Germany	70 (3.7)	76 (4.0)	146 (3.9)
Greece	72 (3.8)	62 (3.3)	134 (3.6)
Hungary	67 (3.6)	75 (4.0)	142 (3.8)
India	86 (4.6)	95 (5.1)	181 (4.8)
Israel	20 (1.1)	17 (0.9)	37 (1.0)
Italy	44 (2.3)	42 (2.2)	86 (2.3)
Japan	173 (9.2)	176 (9.4)	349 (9.3)
Korea	23 (1.2)	47 (2.5)	70 (1.9)
Mexico	74 (3.9)	79 (4.2)	153 (4.1)
Netherlands	7 (0.4)	6 (0.3)	13 (0.3)
Poland	112 (6.0)	101 (5.4)	213 (5.7)
Portugal	15 (0.8)	13 (0.7)	28 (0.7)
Romania	22 (1.2)	17 (0.9)	39 (1.0)
Russia	97 (5.2)	115 (6.1)	212 (5.6)
Slovakia	30 (1.6)	33 (1.8)	63 (1.7)
South Africa	25 (1.3)	25 (1.3)	50 (1.3)
Spain	20 (1.1)	16 (0.9)	36 (1.0)
Taiwan	23 (1.2)	22 (1.2)	45 (1.2)
Turkey	42 (2.2)	40 (2.1)	82 (2.2)
Ukraine	18 (1.0)	12 (0.6)	30 (0.8)
United Kingdom	28 (1.5)	20 (1.1)	48 (1.3)
United States	470 (25.0)	464 (24.7)	934 (24.9)

%: Percentage of subjects, N: Number of subjects, SD: Standard deviation, Other race includes American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander. Subjects from France did not report race and ethnicity. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): SEX AGEGR1 AGEGR2 RACE RACE2 ETHNIC REGION1 COUNTRY2 AAGE; criteria: SAFFL == "Y" & POOLGR1 == "T2D pool"
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7.1.16 Baseline characteristics - summary - safety analysis set - phase 3a pool

	Insulin icodec	Daily basal insulin	Total
Number of subjects	2170	2170	4340
Body weight (kg)			
N	2170	2169	4339
Mean (SD)	86.3 (19.9)	85.2 (19.4)	85.7 (19.7)
Median	84.9	83.4	84.0
Min ; max	39.6 ; 208.4	40.8 ; 196.0	39.6 ; 208.4
Body weight (lb)			
N	2170	2169	4339
Mean (SD)	190.2 (43.9)	187.8 (42.8)	189.0 (43.4)
Median	187.2	183.9	185.2
Min ; max	87.3 ; 459.5	89.9 ; 432.0	87.3 ; 459.5
BMI (kg/m^2)			
N	2170	2169	4339
Mean (SD)	30.2 (5.8)	30.0 (5.9)	30.1 (5.9)
Median	29.6	29.4	29.5
Min ; max	15.4 ; 85.6	16.2 ; 69.4	15.4 ; 85.6
BMI (kg/m^2), N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
<25	394 (18.2)	429 (19.8)	823 (19.0)
>=25 - <30	736 (33.9)	747 (34.4)	1483 (34.2)
>=30 - <35	600 (27.6)	572 (26.4)	1172 (27.0)
>=35	440 (20.3)	421 (19.4)	861 (19.8)
Missing	0	1 (0.0)	1 (0.0)
Smoker status, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Current smoker	337 (15.5)	338 (15.6)	675 (15.6)
Never smoked	1233 (56.8)	1233 (56.8)	2466 (56.8)
Previous smoker	600 (27.6)	599 (27.6)	1199 (27.6)
eGFR (mL/min/1.73m^2)			
N	2169	2169	4338
Mean (SD)	87.7 (20.2)	87.0 (20.4)	87.4 (20.3)
Median	91.0	90.0	90.0
Min ; max	19.0 ; 161.0	17.0 ; 149.0	17.0 ; 161.0
Renal function (eGFR, mL/min/1.73m^2), N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Normal (>=90)	1121 (51.7)	1137 (52.4)	2258 (52.0)
Mild impairment (>=60 - <90)	837 (38.6)	791 (36.5)	1628 (37.5)
Moderate impairment (>=30 - <60)	206 (9.5)	237 (10.9)	443 (10.2)
Severe impairment (<30)	5 (0.2)	4 (0.2)	9 (0.2)
Missing	1 (0.0)	1 (0.0)	2 (0.0)
Hepatic function, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Normal	2080 (95.9)	2071 (95.4)	4151 (95.6)
Impaired	8 (0.4)	7 (0.3)	15 (0.3)
Missing	82 (3.8)	92 (4.2)	174 (4.0)

%: Percentage of subjects, BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, SD: Standard deviation. Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. Baseline refers to week 0 except for renal function and hepatic function, these are evaluated at screening. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.1.17 Baseline characteristics - summary - safety analysis set - T2D pool

	Insulin icodec	Daily basal insulin	Total
Number of subjects	1880	1878	3758
Body weight (kg)			
N	1880	1877	3757
Mean (SD)	87.4 (20.0)	86.4 (19.5)	86.9 (19.8)
Median	85.8	84.8	85.3
Min ; max	43.1 ; 208.4	40.8 ; 196.0	40.8 ; 208.4
Body weight (lb)			
N	1880	1877	3757
Mean (SD)	192.8 (44.1)	190.6 (42.9)	191.7 (43.5)
Median	189.2	187.0	188.1
Min ; max	95.0 ; 459.5	89.9 ; 432.0	89.9 ; 459.5
BMI (kg/m^2)			
N	1880	1877	3757
Mean (SD)	30.7 (5.8)	30.6 (5.8)	30.7 (5.8)
Median	30.2	30.0	30.1
Min ; max	15.4 ; 85.6	17.5 ; 69.4	15.4 ; 85.6
BMI (kg/m^2), N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
<25	289 (15.4)	294 (15.7)	583 (15.5)
>=25 - <30	618 (32.9)	645 (34.3)	1263 (33.6)
>=30 - <35	554 (29.5)	531 (28.3)	1085 (28.9)
>=35	419 (22.3)	407 (21.7)	826 (22.0)
Missing	0	1 (0.1)	1 (0.0)
Smoker status, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Current smoker	300 (16.0)	291 (15.5)	591 (15.7)
Never smoked	1034 (55.0)	1041 (55.4)	2075 (55.2)
Previous smoker	546 (29.0)	546 (29.1)	1092 (29.1)
eGFR (mL/min/1.73m^2)			
N	1879	1877	3756
Mean (SD)	86.1 (20.0)	85.5 (20.0)	85.8 (20.0)
Median	89.0	90.0	89.0
Min ; max	19.0 ; 149.0	17.0 ; 147.0	17.0 ; 149.0
Renal function (eGFR, mL/min/1.73m^2), N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Normal (>=90)	924 (49.1)	947 (50.4)	1871 (49.8)
Mild impairment (>=60 - <90)	749 (39.8)	698 (37.2)	1447 (38.5)
Moderate impairment (>=30 - <60)	201 (10.7)	228 (12.1)	429 (11.4)
Severe impairment (<30)	5 (0.3)	4 (0.2)	9 (0.2)
Missing	1 (0.1)	1 (0.1)	2 (0.1)
Hepatic function, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Normal	1799 (95.7)	1786 (95.1)	3585 (95.4)
Impaired	7 (0.4)	7 (0.4)	14 (0.4)
Missing	74 (3.9)	85 (4.5)	159 (4.2)

%: Percentage of subjects, BMI: Body mass index, eGFR: Estimated glomerular filtration rate, N: Number of subjects, SD: Standard deviation, Renal function categories are based on eGFR derived using the 2009 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equation. Impaired hepatic function is defined as having a total score of >2 according to a modified Child-Pugh classification based on low serum albumin and/or increased bilirubin. Baseline refers to week 0 except for renal function and hepatic function, these are evaluated at screening. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.18 Baseline diabetes characteristics - summary - safety analysis set - phase 3a pool

	Insulin icodec	Daily basal insulin	Total
Number of subjects	2170	2170	4340
Duration of diabetes (years)			
N	2170	2170	4340
Mean (SD)	14.2 (9.0)	13.9 (8.7)	14.1 (8.9)
Median	12.4	12.4	12.4
Min ; Max	0.0 ; 59.6	0.2 ; 62.5	0.0 ; 62.5
Duration of diabetes, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
<10 years	764 (35.2)	796 (36.7)	1560 (35.9)
>=10 years	1406 (64.8)	1374 (63.3)	2780 (64.1)
Pre-trial insulin treatment, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
Insulin naive	1327 (61.2)	1324 (61.0)	2651 (61.1)
Basal insulin	262 (12.1)	263 (12.1)	525 (12.1)
Basal-bolus insulin regimen	581 (26.8)	583 (26.9)	1164 (26.8)
HbA1c (%)			
N	2170	2169	4339
Mean (SD)	8.4 (1.2)	8.4 (1.2)	8.4 (1.2)
Median	8.2	8.2	8.2
Min ; Max	5.1 ; 15.8	5.5 ; 16.3	5.1 ; 16.3
HbA1c (mmol/mol)			
N	2170	2169	4339
Mean (SD)	68.7 (13.5)	68.2 (12.8)	68.4 (13.2)
Median	66.1	66.1	66.1
Min ; Max	32.2 ; 149.2	36.6 ; 154.7	32.2 ; 154.7
HbA1c, N (%)			
N	2170 (100.0)	2170 (100.0)	4340 (100.0)
<8% (<64 mmol/mol)	888 (40.9)	897 (41.3)	1785 (41.1)
>=8% (>=64 mmol/mol)	1282 (59.1)	1272 (58.6)	2554 (58.8)
Missing	0	1 (0.0)	1 (0.0)
FPG (mmol/L)			
N	1582	1592	3174
Mean (SD)	9.8 (3.2)	9.6 (3.2)	9.7 (3.2)
Median	9.3	9.2	9.2
Min ; Max	2.4 ; 24.5	2.2 ; 27.7	2.2 ; 27.7
FPG (mg/dL)			
N	1582	1592	3174
Mean (SD)	175.7 (57.0)	173.7 (56.8)	174.7 (56.9)
Median	167.6	165.8	165.8
Min ; Max	43.2 ; 441.5	39.6 ; 499.2	39.6 ; 499.2

%: Percentage of subjects, FPG: Fasting plasma glucose, N: Number of subjects, SD: Standard deviation. The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date. 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): DIABDURY DIABGR1 PRINSTR HBA1CBL HB1CCBL HBAGR1 FPGBL FPGCBL; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"
nn1436/nn1436-iss/submission_20221024_er
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7.1.19 Baseline diabetes characteristics - summary - safety analysis set - T2D pool

	Insulin icodec	Daily basal insulin	Total
Number of subjects	1880	1878	3758
Duration of diabetes (years)			
N	1880	1878	3758
Mean (SD)	13.3 (7.8)	13.1 (7.6)	13.2 (7.7)
Median	11.8	12.1	11.9
Min ; Max	0.0 ; 59.6	0.2 ; 51.5	0.0 ; 59.6
Duration of diabetes, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
<10 years	689 (36.6)	714 (38.0)	1403 (37.3)
>=10 years	1191 (63.4)	1164 (62.0)	2355 (62.7)
Pre-trial insulin treatment, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
Insulin naive	1327 (70.6)	1324 (70.5)	2651 (70.5)
Basal insulin	262 (13.9)	263 (14.0)	525 (14.0)
Basal-bolus insulin regimen	291 (15.5)	291 (15.5)	582 (15.5)
HbA1c (%)			
N	1880	1877	3757
Mean (SD)	8.6 (1.2)	8.5 (1.2)	8.5 (1.2)
Median	8.3	8.3	8.3
Min ; Max	6.3 ; 15.8	6.4 ; 16.3	6.3 ; 16.3
HbA1c (mmol/mol)			
N	1880	1877	3757
Mean (SD)	70.1 (13.3)	69.5 (12.7)	69.8 (13.0)
Median	67.2	67.2	67.2
Min ; Max	45.4 ; 149.2	46.5 ; 154.7	45.4 ; 154.7
HbA1c, N (%)			
N	1880 (100.0)	1878 (100.0)	3758 (100.0)
<8% (<64 mmol/mol)	699 (37.2)	708 (37.7)	1407 (37.4)
>=8% (>=64 mmol/mol)	1181 (62.8)	1169 (62.2)	2350 (62.5)
Missing	0	1 (0.1)	1 (0.0)
FPG (mmol/L)			
N	1306	1305	2611
Mean (SD)	9.7 (2.9)	9.7 (2.9)	9.7 (2.9)
Median	9.3	9.2	9.2
Min ; Max	3.1 ; 24.3	2.9 ; 24.2	2.9 ; 24.3
FPG (mg/dL)			
N	1306	1305	2611
Mean (SD)	175.0 (52.8)	173.9 (52.9)	174.5 (52.8)
Median	167.6	165.8	165.8
Min ; Max	55.9 ; 437.9	52.3 ; 436.1	52.3 ; 437.9

%: Percentage of subjects, FPG: Fasting plasma glucose, N: Number of subjects, SD: Standard deviation, The duration of diabetes is calculated as the time from date of diagnosis to the randomisation date. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.20 Diabetes complications before or at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec			Daily basal insulin			Total		
	N	(%)	E	N	(%)	E	N	(%)	E
Number of subjects	2170			2170			4340		
All complications	792	(36.5)	1374	777	(35.8)	1382	1569	(36.1)	2756
Diabetic neuropathy	522	(24.1)	539	492	(22.7)	511	1014	(23.4)	1050
Diabetic retinopathy	317	(14.6)	593	341	(15.7)	646	658	(15.2)	1239
Diabetic nephropathy	236	(10.9)	242	224	(10.3)	225	460	(10.6)	467

%: Percentage of subjects, E: Number of events, N: Number of subjects. 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): NA; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHDECOD; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y" & ASCRF %in% c("COMPLETED BEFORE", "ONGOING"))
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7.1.21 Diabetes complications before or at screening - summary - safety analysis set - T2D pool

	Insulin icodec			Daily basal insulin			Total		
	N	(%)	E	N	(%)	E	N	(%)	E
Number of subjects	1880			1878			3758		
All complications	687	(36.5)	1172	683	(36.4)	1186	1370	(36.5)	2358
Diabetic neuropathy	455	(24.2)	470	433	(23.1)	446	888	(23.6)	916
Diabetic retinopathy	260	(13.8)	486	281	(15.0)	533	541	(14.4)	1019
Diabetic nephropathy	211	(11.2)	216	206	(11.0)	207	417	(11.1)	423

%: Percentage of subjects, E: Number of events, N: Number of subjects, Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): NA; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHDECOD; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y" & ASCRF %in% c("COMPLETED BEFORE", "ONGOING"))
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7.1.22 Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	2170		2170		4340	
All illnesses	2079	(95.8)	2077	(95.7)	4156	(95.8)
Metabolism And Nutrition Disorders	1617	(74.5)	1620	(74.7)	3237	(74.6)
Dyslipidaemia	707	(32.6)	704	(32.4)	1411	(32.5)
Hyperlipidaemia	542	(25.0)	563	(25.9)	1105	(25.5)
Obesity	391	(18.0)	371	(17.1)	762	(17.6)
Hypercholesterolaemia	222	(10.2)	207	(9.5)	429	(9.9)
Vitamin D Deficiency	149	(6.9)	118	(5.4)	267	(6.2)
Hyperuricaemia	93	(4.3)	100	(4.6)	193	(4.5)
Hypertriglyceridaemia	56	(2.6)	67	(3.1)	123	(2.8)
Gout	42	(1.9)	57	(2.6)	99	(2.3)
Overweight	41	(1.9)	29	(1.3)	70	(1.6)
Vitamin B12 Deficiency	30	(1.4)	20	(0.9)	50	(1.1)
Metabolic Syndrome	11	(0.5)	10	(0.5)	21	(0.5)
Lipid Metabolism Disorder	10	(0.5)	7	(0.3)	17	(0.4)
Iron Deficiency	6	(0.3)	10	(0.5)	16	(0.4)
Central Obesity	7	(0.3)	4	(0.2)	11	(0.2)
Hypokalaemia	3	(0.1)	7	(0.3)	10	(0.2)
Lactose Intolerance	7	(0.3)	3	(0.1)	10	(0.2)
Hypercalcaemia	5	(0.2)	4	(0.2)	9	(0.2)
Hyperkalaemia	5	(0.2)	4	(0.2)	9	(0.2)
Hyponatraemia	4	(0.2)	4	(0.2)	8	(0.2)
Vitamin B Complex Deficiency	6	(0.3)	2	(0.1)	8	(0.2)
Hypomagnesaemia	3	(0.1)	3	(0.1)	6	(0.1)
Abnormal Weight Gain	2	(0.1)	1	(0.1)	3	(0.1)
Calcium Deficiency	3	(0.1)	0		3	(0.1)
Diabetic Dyslipidaemia	3	(0.1)	0		3	(0.1)
Folate Deficiency	3	(0.1)	0		3	(0.1)
Hyperglycaemia	1	(0.1)	2	(0.1)	3	(0.1)
Hypochloraemia	1	(0.1)	2	(0.1)	3	(0.1)
Hypovitaminosis	1	(0.1)	2	(0.1)	3	(0.1)
Haemochromatosis	2	(0.1)	0		2	(0.1)
Hyperhomocysteinaemia	1	(0.1)	1	(0.1)	2	(0.1)
Hypocholesterolaemia	0		2	(0.1)	2	(0.1)
Hypoglycaemia	0		2	(0.1)	2	(0.1)
Insulin Resistance	2	(0.1)	0		2	(0.1)
Cholesterosis	0		1	(0.1)	1	(0.0)
Decreased Appetite	1	(0.1)	0		1	(0.0)
Diabetic Ketosis	0		1	(0.1)	1	(0.0)
Glucose Tolerance Impaired	0		1	(0.1)	1	(0.0)
Histamine Intolerance	0		1	(0.1)	1	(0.0)
Hyperinsulinaemia	0		1	(0.1)	1	(0.0)
Hypoalbuminaemia	1	(0.1)	0		1	(0.0)
Hypocalcaemia	1	(0.1)	0		1	(0.0)
Hypolipidaemia	0		1	(0.1)	1	(0.0)
Hypoproteinaemia	0		1	(0.1)	1	(0.0)
Lipoedema	1	(0.1)	0		1	(0.0)
Lipomatosis	0		1	(0.1)	1	(0.0)
Magnesium Deficiency	0		1	(0.1)	1	(0.0)
Metabolic Disorder	1	(0.1)	0		1	(0.0)
Mineral Metabolism Disorder	0		1	(0.1)	1	(0.0)
Polydipsia	0		1	(0.1)	1	(0.0)
Tetany	1	(0.1)	0		1	(0.0)
Underweight	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vascular Disorders	1525	(70.3)	1497	(69.0)	3022	(69.6)
Hypertension	1469	(67.7)	1431	(65.9)	2900	(66.8)
Peripheral Arterial Occlusive Disease	91	(4.2)	97	(4.5)	188	(4.3)
Varicose Vein	56	(2.6)	57	(2.6)	113	(2.6)
Peripheral Venous Disease	40	(1.8)	32	(1.5)	72	(1.7)
Aortic Arteriosclerosis	20	(0.9)	33	(1.5)	53	(1.2)
Arteriosclerosis	20	(0.9)	25	(1.1)	45	(1.0)
Hypertensive Angiopathy	17	(0.8)	23	(1.1)	40	(0.9)
Diabetic Vascular Disorder	8	(0.4)	14	(0.7)	22	(0.5)
Peripheral Vascular Disorder	5	(0.2)	8	(0.4)	13	(0.3)
Hot Flush	6	(0.3)	5	(0.2)	11	(0.2)
Peripheral Artery Stenosis	6	(0.3)	5	(0.2)	11	(0.2)
Deep Vein Thrombosis	3	(0.1)	7	(0.3)	10	(0.2)
Essential Hypertension	2	(0.1)	7	(0.3)	9	(0.2)
Aortic Dilatation	3	(0.1)	5	(0.2)	8	(0.2)
Aortic Stenosis	4	(0.2)	3	(0.1)	7	(0.2)
Aortic Aneurysm	4	(0.2)	2	(0.1)	6	(0.1)
Brachiocephalic Arteriosclerosis	2	(0.1)	3	(0.1)	5	(0.1)
Raynaud's Phenomenon	2	(0.1)	3	(0.1)	5	(0.1)
Angiopathy	3	(0.1)	1	(0.1)	4	(0.1)
Lymphoedema	3	(0.1)	1	(0.1)	4	(0.1)
Orthostatic Hypotension	3	(0.1)	1	(0.1)	4	(0.1)
Embolism Venous	0		3	(0.1)	3	(0.1)
Macroangiopathy	3	(0.1)	0		3	(0.1)
Thrombophlebitis	1	(0.1)	2	(0.1)	3	(0.1)
Aortic Dissection	2	(0.1)	0		2	(0.1)
Diabetic Macroangiopathy	2	(0.1)	0		2	(0.1)
Hypotension	1	(0.1)	1	(0.1)	2	(0.1)
Aneurysm	0		1	(0.1)	1	(0.0)
Angiosclerosis	0		1	(0.1)	1	(0.0)
Aortic Disorder	1	(0.1)	0		1	(0.0)
Aortic Thrombosis	1	(0.1)	0		1	(0.0)
Arterial Insufficiency	1	(0.1)	0		1	(0.0)
Arterial Occlusive Disease	1	(0.1)	0		1	(0.0)
Arteriosclerosis Moenckeberg-Type	1	(0.1)	0		1	(0.0)
Atheroembolism	0		1	(0.1)	1	(0.0)
Diabetic Microangiopathy	0		1	(0.1)	1	(0.0)
Giant Cell Arteritis	0		1	(0.1)	1	(0.0)
Granulomatosis With Polyangiitis	0		1	(0.1)	1	(0.0)
Iliac Artery Stenosis	0		1	(0.1)	1	(0.0)
Jugular Vein Distension	0		1	(0.1)	1	(0.0)
Leriche Syndrome	1	(0.1)	0		1	(0.0)
May-Thurner Syndrome	1	(0.1)	0		1	(0.0)
Phlebitis	1	(0.1)	0		1	(0.0)
Poor Peripheral Circulation	1	(0.1)	0		1	(0.0)
Post Thrombotic Syndrome	0		1	(0.1)	1	(0.0)
Spider Vein	1	(0.1)	0		1	(0.0)
Subclavian Artery Stenosis	1	(0.1)	0		1	(0.0)
Subclavian Steal Syndrome	1	(0.1)	0		1	(0.0)
Venous Thrombosis	0		1	(0.1)	1	(0.0)
White Coat Hypertension	1	(0.1)	0		1	(0.0)
Eye Disorders	796	(36.7)	812	(37.4)	1608	(37.0)
Diabetic Retinopathy	365	(16.8)	380	(17.5)	745	(17.2)
Cataract	301	(13.9)	296	(13.6)	597	(13.8)
Glaucoma	90	(4.2)	88	(4.1)	178	(4.1)
Myopia	80	(3.7)	84	(3.9)	164	(3.8)
Presbyopia	59	(2.7)	80	(3.7)	139	(3.2)
Astigmatism	47	(2.2)	53	(2.4)	100	(2.3)
Retinopathy Hypertensive	49	(2.3)	46	(2.1)	95	(2.2)
Hypermetropia	41	(1.9)	49	(2.3)	90	(2.1)
Dry Eye	40	(1.8)	45	(2.1)	85	(2.0)
Diabetic Retinal Oedema	34	(1.6)	37	(1.7)	71	(1.6)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Conjunctivitis Allergic	14	(0.7)	14	(0.7)	28	(0.7)
Macular Degeneration	9	(0.4)	19	(0.9)	28	(0.7)
Retinal Vascular Disorder	11	(0.5)	17	(0.8)	28	(0.7)
Refraction Disorder	11	(0.5)	14	(0.7)	25	(0.6)
Cataract Nuclear	14	(0.7)	10	(0.5)	24	(0.6)
Arteriosclerotic Retinopathy	12	(0.6)	10	(0.5)	22	(0.5)
Ocular Hypertension	13	(0.6)	9	(0.4)	22	(0.5)
Vitreous Detachment	10	(0.5)	9	(0.4)	19	(0.4)
Age-Related Macular Degeneration	8	(0.4)	9	(0.4)	17	(0.4)
Epiretinal Membrane	10	(0.5)	7	(0.3)	17	(0.4)
Visual Acuity Reduced	8	(0.4)	8	(0.4)	16	(0.4)
Amblyopia	7	(0.3)	7	(0.3)	14	(0.3)
Vitreous Degeneration	4	(0.2)	10	(0.5)	14	(0.3)
Chorioretinal Disorder	5	(0.2)	8	(0.4)	13	(0.3)
Vitreous Floaters	10	(0.5)	3	(0.1)	13	(0.3)
Blepharitis	3	(0.1)	8	(0.4)	11	(0.2)
Eye Disorder	4	(0.2)	5	(0.2)	9	(0.2)
Asthenopia	5	(0.2)	3	(0.1)	8	(0.2)
Retinal Drusen	3	(0.1)	5	(0.2)	8	(0.2)
Blindness Unilateral	4	(0.2)	3	(0.1)	7	(0.2)
Dry Age-Related Macular Degeneration	2	(0.1)	5	(0.2)	7	(0.2)
Retinal Degeneration	3	(0.1)	4	(0.2)	7	(0.2)
Strabismus	2	(0.1)	5	(0.2)	7	(0.2)
Vitreous Disorder	5	(0.2)	2	(0.1)	7	(0.2)
Vitreous Opacities	3	(0.1)	4	(0.2)	7	(0.2)
Chorioretinal Atrophy	1	(0.1)	5	(0.2)	6	(0.1)
Keratitis	3	(0.1)	3	(0.1)	6	(0.1)
Macular Oedema	4	(0.2)	2	(0.1)	6	(0.1)
Pterygium	3	(0.1)	3	(0.1)	6	(0.1)
Retinal Aneurysm	4	(0.2)	2	(0.1)	6	(0.1)
Xerophthalmia	5	(0.2)	1	(0.1)	6	(0.1)
Corneal Opacity	3	(0.1)	2	(0.1)	5	(0.1)
Maculopathy	3	(0.1)	2	(0.1)	5	(0.1)
Optic Atrophy	4	(0.2)	1	(0.1)	5	(0.1)
Retinal Detachment	3	(0.1)	2	(0.1)	5	(0.1)
Retinal Disorder	4	(0.2)	1	(0.1)	5	(0.1)
Vision Blurred	3	(0.1)	2	(0.1)	5	(0.1)
Visual Impairment	5	(0.2)	0		5	(0.1)
Dermatochalasis	2	(0.1)	2	(0.1)	4	(0.1)
Hyalosis Asteroid	1	(0.1)	3	(0.1)	4	(0.1)
Meibomian Gland Dysfunction	1	(0.1)	3	(0.1)	4	(0.1)
Retinal Haemorrhage	2	(0.1)	2	(0.1)	4	(0.1)
Retinal Tear	2	(0.1)	2	(0.1)	4	(0.1)
Retinal Vein Occlusion	0		4	(0.2)	4	(0.1)
Conjunctivochalasis	1	(0.1)	2	(0.1)	3	(0.1)
Ectropion	1	(0.1)	2	(0.1)	3	(0.1)
Endocrine Ophthalmopathy	2	(0.1)	1	(0.1)	3	(0.1)
Exfoliation Syndrome	1	(0.1)	2	(0.1)	3	(0.1)
Eyelid Ptosis	2	(0.1)	1	(0.1)	3	(0.1)
Neovascular Age-Related Macular Degeneration	2	(0.1)	1	(0.1)	3	(0.1)
Optic Nerve Cupping	2	(0.1)	1	(0.1)	3	(0.1)
Posterior Capsule Opacification	1	(0.1)	2	(0.1)	3	(0.1)
Retinal Depigmentation	2	(0.1)	1	(0.1)	3	(0.1)
Retinal Dystrophy	1	(0.1)	2	(0.1)	3	(0.1)
Retinal Fibrosis	1	(0.1)	2	(0.1)	3	(0.1)
Retinopathy	1	(0.1)	2	(0.1)	3	(0.1)
Aphakia	2	(0.1)	0		2	(0.1)
Blindness	0		2	(0.1)	2	(0.1)
Chalazion	0		2	(0.1)	2	(0.1)
Chorioretinal Scar	1	(0.1)	1	(0.1)	2	(0.1)
Chorioretinopathy	0		2	(0.1)	2	(0.1)
Corneal Erosion	1	(0.1)	1	(0.1)	2	(0.1)
Diplopia	0		2	(0.1)	2	(0.1)
Eye Discharge	2	(0.1)	0		2	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Eye Haemorrhage	0		2	(0.1)	2	(0.1)
Eyelid Cyst	2	(0.1)	0		2	(0.1)
Eyelid Disorder	0		2	(0.1)	2	(0.1)
Iritis	0		2	(0.1)	2	(0.1)
Keratoconus	2	(0.1)	0		2	(0.1)
Macular Scar	1	(0.1)	1	(0.1)	2	(0.1)
Mydriasis	2	(0.1)	0		2	(0.1)
Non-Proliferative Retinopathy	1	(0.1)	1	(0.1)	2	(0.1)
Ocular Discomfort	1	(0.1)	1	(0.1)	2	(0.1)
Open Angle Glaucoma	1	(0.1)	1	(0.1)	2	(0.1)
Optic Disc Drusen	1	(0.1)	1	(0.1)	2	(0.1)
Visual Field Defect	0		2	(0.1)	2	(0.1)
Vitreous Haemorrhage	0		2	(0.1)	2	(0.1)
Amaurosis	1	(0.1)	0		1	(0.0)
Amaurosis Fugax	1	(0.1)	0		1	(0.0)
Angle Closure Glaucoma	0		1	(0.1)	1	(0.0)
Anisometropia	0		1	(0.1)	1	(0.0)
Arcus Lipoides	1	(0.1)	0		1	(0.0)
Cataract Cortical	1	(0.1)	0		1	(0.0)
Cataract Subcapsular	1	(0.1)	0		1	(0.0)
Cholesterolosis Bulbi	0		1	(0.1)	1	(0.0)
Choroidal Dystrophy	0		1	(0.1)	1	(0.0)
Corneal Defect	1	(0.1)	0		1	(0.0)
Corneal Disorder	0		1	(0.1)	1	(0.0)
Corneal Oedema	1	(0.1)	0		1	(0.0)
Corneal Scar	1	(0.1)	0		1	(0.0)
Detachment Of Retinal Pigment Epithelium	1	(0.1)	0		1	(0.0)
Diabetic Eye Disease	1	(0.1)	0		1	(0.0)
Eczema Eyelids	1	(0.1)	0		1	(0.0)
Episcleritis	0		1	(0.1)	1	(0.0)
Exophthalmos	0		1	(0.1)	1	(0.0)
Eye Pain	0		1	(0.1)	1	(0.0)
Eye Swelling	1	(0.1)	0		1	(0.0)
Flat Anterior Chamber Of Eye	0		1	(0.1)	1	(0.0)
Floppy Eyelid Syndrome	0		1	(0.1)	1	(0.0)
Heterophoria	0		1	(0.1)	1	(0.0)
Iris Neovascularisation	1	(0.1)	0		1	(0.0)
Lacrimal Disorder	0		1	(0.1)	1	(0.0)
Lacrimation Decreased	0		1	(0.1)	1	(0.0)
Lacrimation Increased	1	(0.1)	0		1	(0.0)
Lens Disorder	0		1	(0.1)	1	(0.0)
Lenticular Opacities	0		1	(0.1)	1	(0.0)
Macular Cyst	0		1	(0.1)	1	(0.0)
Macular Hole	1	(0.1)	0		1	(0.0)
Myopic Chorioretinal Degeneration	1	(0.1)	0		1	(0.0)
Narrow Anterior Chamber Angle	1	(0.1)	0		1	(0.0)
Normal Tension Glaucoma	1	(0.1)	0		1	(0.0)
Optic Disc Haemorrhage	0		1	(0.1)	1	(0.0)
Pigment Dispersion Syndrome	0		1	(0.1)	1	(0.0)
Pinguecula	0		1	(0.1)	1	(0.0)
Pupils Unequal	1	(0.1)	0		1	(0.0)
Retinal Artery Embolism	1	(0.1)	0		1	(0.0)
Retinal Artery Occlusion	0		1	(0.1)	1	(0.0)
Retinal Exudates	1	(0.1)	0		1	(0.0)
Retinal Oedema	1	(0.1)	0		1	(0.0)
Retinal Pigment Epitheliopathy	0		1	(0.1)	1	(0.0)
Retinal Scar	0		1	(0.1)	1	(0.0)
Retinal Vascular Thrombosis	0		1	(0.1)	1	(0.0)
Retinopathy Proliferative	0		1	(0.1)	1	(0.0)
Scleritis	0		1	(0.1)	1	(0.0)
Subretinal Fibrosis	1	(0.1)	0		1	(0.0)
Swelling Of Eyelid	1	(0.1)	0		1	(0.0)
Symblepharon	1	(0.1)	0		1	(0.0)
Uveitis	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitreous Loss	0		1	(0.1)	1	(0.0)
Nervous System Disorders	766	(35.3)	764	(35.2)	1530	(35.2)
Diabetic Neuropathy	502	(23.1)	481	(22.2)	983	(22.6)
Headache	43	(2.0)	55	(2.5)	98	(2.3)
Migraine	41	(1.9)	55	(2.5)	96	(2.2)
Carotid Artery Stenosis	31	(1.4)	34	(1.6)	65	(1.5)
Carotid Arteriosclerosis	27	(1.2)	33	(1.5)	60	(1.4)
Carpal Tunnel Syndrome	27	(1.2)	24	(1.1)	51	(1.2)
Diabetic Autonomic Neuropathy	24	(1.1)	18	(0.8)	42	(1.0)
Sciatica	25	(1.1)	17	(0.8)	42	(1.0)
Myelopathy	23	(1.1)	13	(0.6)	36	(0.8)
Cerebrovascular Accident	14	(0.7)	21	(1.0)	35	(0.8)
Restless Legs Syndrome	13	(0.6)	18	(0.8)	31	(0.7)
Cerebrovascular Disorder	11	(0.5)	17	(0.8)	28	(0.7)
Cerebral Arteriosclerosis	5	(0.2)	19	(0.9)	24	(0.6)
Encephalopathy	7	(0.3)	17	(0.8)	24	(0.6)
Neuropathy Peripheral	17	(0.8)	7	(0.3)	24	(0.6)
Dizziness	14	(0.7)	9	(0.4)	23	(0.5)
Cerebral Ischaemia	6	(0.3)	15	(0.7)	21	(0.5)
Carotid Artery Occlusion	4	(0.2)	16	(0.7)	20	(0.5)
Tension Headache	3	(0.1)	15	(0.7)	18	(0.4)
Essential Tremor	8	(0.4)	9	(0.4)	17	(0.4)
Cervicobrachial Syndrome	11	(0.5)	5	(0.2)	16	(0.4)
Vascular Encephalopathy	4	(0.2)	10	(0.5)	14	(0.3)
Cervical Radiculopathy	6	(0.3)	7	(0.3)	13	(0.3)
Paraesthesia	8	(0.4)	5	(0.2)	13	(0.3)
Vertebrobasilar Insufficiency	8	(0.4)	4	(0.2)	12	(0.3)
Amnesia	3	(0.1)	8	(0.4)	11	(0.2)
Cauda Equina Syndrome	5	(0.2)	4	(0.2)	9	(0.2)
Hypoaesthesia	4	(0.2)	5	(0.2)	9	(0.2)
Hyporeflexia	4	(0.2)	5	(0.2)	9	(0.2)
Lumbar Radiculopathy	5	(0.2)	4	(0.2)	9	(0.2)
Polyneuropathy	2	(0.1)	7	(0.3)	9	(0.2)
Bell's Palsy	4	(0.2)	4	(0.2)	8	(0.2)
Epilepsy	3	(0.1)	4	(0.2)	7	(0.2)
Autonomic Nervous System Imbalance	3	(0.1)	3	(0.1)	6	(0.1)
Nerve Compression	1	(0.1)	5	(0.2)	6	(0.1)
Neuralgia	3	(0.1)	3	(0.1)	6	(0.1)
Radiculopathy	1	(0.1)	5	(0.2)	6	(0.1)
Cerebral Infarction	2	(0.1)	3	(0.1)	5	(0.1)
Hypersomnia	2	(0.1)	3	(0.1)	5	(0.1)
Transient Ischaemic Attack	4	(0.2)	1	(0.1)	5	(0.1)
Cerebrovascular Insufficiency	1	(0.1)	3	(0.1)	4	(0.1)
Diabetic Encephalopathy	0		4	(0.2)	4	(0.1)
Intracranial Aneurysm	2	(0.1)	2	(0.1)	4	(0.1)
Lumbosacral Radiculopathy	1	(0.1)	3	(0.1)	4	(0.1)
Memory Impairment	2	(0.1)	2	(0.1)	4	(0.1)
Muscle Tone Disorder	2	(0.1)	2	(0.1)	4	(0.1)
Parkinson's Disease	3	(0.1)	1	(0.1)	4	(0.1)
Tremor	3	(0.1)	1	(0.1)	4	(0.1)
Balance Disorder	0		3	(0.1)	3	(0.1)
Brain Stem Ischaemia	1	(0.1)	2	(0.1)	3	(0.1)
Cerebral Atrophy	3	(0.1)	0		3	(0.1)
Hypertonia	0		3	(0.1)	3	(0.1)
Seizure	3	(0.1)	0		3	(0.1)
Sensory Disturbance	1	(0.1)	2	(0.1)	3	(0.1)
Sinus Headache	3	(0.1)	0		3	(0.1)
Cerebral Artery Stenosis	0		2	(0.1)	2	(0.1)
Cognitive Disorder	2	(0.1)	0		2	(0.1)
Decreased Vibratory Sense	1	(0.1)	1	(0.1)	2	(0.1)
Dementia	2	(0.1)	0		2	(0.1)
Guillain-Barre Syndrome	1	(0.1)	1	(0.1)	2	(0.1)
Hemiparesis	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Intercostal Neuralgia	1	(0.1)	1	(0.1)	2	(0.1)
Migraine Without Aura	0		2	(0.1)	2	(0.1)
Mononeuropathy	1	(0.1)	1	(0.1)	2	(0.1)
Multiple Sclerosis	1	(0.1)	1	(0.1)	2	(0.1)
Ophthalmic Migraine	1	(0.1)	1	(0.1)	2	(0.1)
Peripheral Sensory Neuropathy	0		2	(0.1)	2	(0.1)
Post Herpetic Neuralgia	0		2	(0.1)	2	(0.1)
Somnolence	1	(0.1)	1	(0.1)	2	(0.1)
Syncope	0		2	(0.1)	2	(0.1)
Trigeminal Neuralgia	1	(0.1)	1	(0.1)	2	(0.1)
Vertebral Artery Stenosis	1	(0.1)	1	(0.1)	2	(0.1)
Anosmia	0		1	(0.1)	1	(0.0)
Arachnoid Cyst	0		1	(0.1)	1	(0.0)
Brain Stem Infarction	1	(0.1)	0		1	(0.0)
Carotid Artery Disease	0		1	(0.1)	1	(0.0)
Carotid Artery Thrombosis	0		1	(0.1)	1	(0.0)
Central Nervous System Lesion	0		1	(0.1)	1	(0.0)
Central Nervous System Vasculitis	1	(0.1)	0		1	(0.0)
Cerebellar Syndrome	0		1	(0.1)	1	(0.0)
Cerebral Calcification	1	(0.1)	0		1	(0.0)
Cerebral Small Vessel Ischaemic Disease	1	(0.1)	0		1	(0.0)
Cerebral Ventricle Dilatation	0		1	(0.1)	1	(0.0)
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	1	(0.1)	0		1	(0.0)
Complex Regional Pain Syndrome	1	(0.1)	0		1	(0.0)
Cubital Tunnel Syndrome	1	(0.1)	0		1	(0.0)
Demyelination	1	(0.1)	0		1	(0.0)
Disturbance In Attention	1	(0.1)	0		1	(0.0)
Dizziness Postural	0		1	(0.1)	1	(0.0)
Dyskinesia	1	(0.1)	0		1	(0.0)
Facial Nerve Disorder	0		1	(0.1)	1	(0.0)
Gliosis	1	(0.1)	0		1	(0.0)
Hypokinesia	1	(0.1)	0		1	(0.0)
Internal Carotid Artery Deformity	0		1	(0.1)	1	(0.0)
Leukoencephalopathy	1	(0.1)	0		1	(0.0)
Lumbosacral Radiculoplexus Neuropathy	0		1	(0.1)	1	(0.0)
Meningeal Disorder	1	(0.1)	0		1	(0.0)
Migraine With Aura	0		1	(0.1)	1	(0.0)
Morton's Neuralgia	1	(0.1)	0		1	(0.0)
Myasthenia Gravis	1	(0.1)	0		1	(0.0)
Myoclonus	0		1	(0.1)	1	(0.0)
Neuritis	0		1	(0.1)	1	(0.0)
Occipital Neuralgia	0		1	(0.1)	1	(0.0)
Oromandibular Dystonia	1	(0.1)	0		1	(0.0)
Parkinsonism	0		1	(0.1)	1	(0.0)
Peripheral Motor Neuropathy	0		1	(0.1)	1	(0.0)
Peripheral Nerve Lesion	1	(0.1)	0		1	(0.0)
Peripheral Sensorimotor Neuropathy	0		1	(0.1)	1	(0.0)
Peroneal Nerve Palsy	1	(0.1)	0		1	(0.0)
Phantom Limb Syndrome	0		1	(0.1)	1	(0.0)
Pineal Gland Cyst	0		1	(0.1)	1	(0.0)
Piriformis Syndrome	1	(0.1)	0		1	(0.0)
Post Polio Syndrome	0		1	(0.1)	1	(0.0)
Presyncope	0		1	(0.1)	1	(0.0)
Resting Tremor	0		1	(0.1)	1	(0.0)
Spinal Claudication	1	(0.1)	0		1	(0.0)
Ulnar Nerve Palsy	0		1	(0.1)	1	(0.0)
Ulnar Tunnel Syndrome	0		1	(0.1)	1	(0.0)
Vascular Headache	1	(0.1)	0		1	(0.0)
Vertebral Artery Occlusion	1	(0.1)	0		1	(0.0)
Vith Nerve Paralysis	1	(0.1)	0		1	(0.0)
White Matter Lesion	1	(0.1)	0		1	(0.0)
Musculoskeletal And Connective Tissue	674	(31.1)	690	(31.8)	1364	(31.4)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Disorders						
Osteoarthritis	210	(9.7)	203	(9.3)	413	(9.5)
Back Pain	120	(5.5)	139	(6.4)	259	(6.0)
Arthralgia	84	(3.9)	79	(3.6)	163	(3.8)
Spinal Osteoarthritis	52	(2.4)	54	(2.5)	106	(2.4)
Intervertebral Disc Protrusion	46	(2.1)	58	(2.7)	104	(2.4)
Arthritis	42	(1.9)	43	(2.0)	85	(2.0)
Osteoporosis	36	(1.7)	42	(1.9)	78	(1.8)
Osteochondrosis	26	(1.2)	37	(1.7)	63	(1.4)
Muscle Spasms	30	(1.4)	31	(1.4)	61	(1.4)
Foot Deformity	20	(0.9)	34	(1.6)	54	(1.2)
Intervertebral Disc Degeneration	26	(1.2)	21	(1.0)	47	(1.1)
Osteopenia	25	(1.1)	21	(1.0)	46	(1.1)
Intervertebral Disc Disorder	23	(1.1)	18	(0.8)	41	(0.9)
Neck Pain	23	(1.1)	17	(0.8)	40	(0.9)
Periarthritis	18	(0.8)	17	(0.8)	35	(0.8)
Pain In Extremity	19	(0.9)	15	(0.7)	34	(0.8)
Rotator Cuff Syndrome	14	(0.7)	20	(0.9)	34	(0.8)
Myalgia	9	(0.4)	23	(1.1)	32	(0.7)
Fibromyalgia	15	(0.7)	16	(0.7)	31	(0.7)
Rheumatoid Arthritis	15	(0.7)	16	(0.7)	31	(0.7)
Scoliosis	16	(0.7)	11	(0.5)	27	(0.6)
Back Disorder	11	(0.5)	12	(0.6)	23	(0.5)
Tendonitis	10	(0.5)	12	(0.6)	22	(0.5)
Trigger Finger	12	(0.6)	9	(0.4)	21	(0.5)
Spinal Pain	9	(0.4)	11	(0.5)	20	(0.5)
Spinal Stenosis	11	(0.5)	9	(0.4)	20	(0.5)
Bursitis	7	(0.3)	11	(0.5)	18	(0.4)
Exostosis	11	(0.5)	7	(0.3)	18	(0.4)
Plantar Fasciitis	10	(0.5)	6	(0.3)	16	(0.4)
Psoriatic Arthropathy	9	(0.4)	4	(0.2)	13	(0.3)
Dupuytren's Contracture	7	(0.3)	5	(0.2)	12	(0.3)
Lumbar Spinal Stenosis	6	(0.3)	6	(0.3)	12	(0.3)
Neuropathic Arthropathy	4	(0.2)	7	(0.3)	11	(0.2)
Spondylolisthesis	5	(0.2)	6	(0.3)	11	(0.2)
Gouty Arthritis	4	(0.2)	6	(0.3)	10	(0.2)
Diastasis Recti Abdominis	4	(0.2)	5	(0.2)	9	(0.2)
Tenosynovitis	2	(0.1)	6	(0.3)	8	(0.2)
Acquired Claw Toe	4	(0.2)	3	(0.1)	7	(0.2)
Joint Range Of Motion Decreased	3	(0.1)	4	(0.2)	7	(0.2)
Spondylitis	3	(0.1)	4	(0.2)	7	(0.2)
Synovial Cyst	4	(0.2)	3	(0.1)	7	(0.2)
Ankylosing Spondylitis	2	(0.1)	4	(0.2)	6	(0.1)
Arthropathy	1	(0.1)	5	(0.2)	6	(0.1)
Cervical Spinal Stenosis	2	(0.1)	4	(0.2)	6	(0.1)
Musculoskeletal Stiffness	2	(0.1)	4	(0.2)	6	(0.1)
Patellofemoral Pain Syndrome	1	(0.1)	5	(0.2)	6	(0.1)
Polyarthritis	4	(0.2)	2	(0.1)	6	(0.1)
Musculoskeletal Chest Pain	2	(0.1)	3	(0.1)	5	(0.1)
Musculoskeletal Pain	2	(0.1)	3	(0.1)	5	(0.1)
Temporomandibular Joint Syndrome	4	(0.2)	1	(0.1)	5	(0.1)
Tendon Disorder	4	(0.2)	1	(0.1)	5	(0.1)
Enthesopathy	3	(0.1)	1	(0.1)	4	(0.1)
Meniscopathy	2	(0.1)	2	(0.1)	4	(0.1)
Sacroiliitis	2	(0.1)	2	(0.1)	4	(0.1)
Tenosynovitis Stenosans	1	(0.1)	3	(0.1)	4	(0.1)
Chondromalacia	3	(0.1)	0		3	(0.1)
Chondropathy	1	(0.1)	2	(0.1)	3	(0.1)
Facet Joint Syndrome	2	(0.1)	1	(0.1)	3	(0.1)
Metatarsalgia	2	(0.1)	1	(0.1)	3	(0.1)
Myofascial Pain Syndrome	2	(0.1)	1	(0.1)	3	(0.1)
Nodal Osteoarthritis	3	(0.1)	0		3	(0.1)
Osteochondritis	1	(0.1)	2	(0.1)	3	(0.1)
Polymyalgia Rheumatica	2	(0.1)	1	(0.1)	3	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Sjogren's Syndrome	0		3	(0.1)	3	(0.1)
Synovitis	2	(0.1)	1	(0.1)	3	(0.1)
Systemic Lupus Erythematosus	3	(0.1)	0		3	(0.1)
Bone Formation Increased	1	(0.1)	1	(0.1)	2	(0.1)
Bone Hypertrophy	2	(0.1)	0		2	(0.1)
Flank Pain	2	(0.1)	0		2	(0.1)
Knee Deformity	0		2	(0.1)	2	(0.1)
Kyphosis	2	(0.1)	0		2	(0.1)
Muscular Weakness	0		2	(0.1)	2	(0.1)
Myofascitis	1	(0.1)	1	(0.1)	2	(0.1)
Myopathy	1	(0.1)	1	(0.1)	2	(0.1)
Neck Mass	2	(0.1)	0		2	(0.1)
Plantar Fascial Fibromatosis	1	(0.1)	1	(0.1)	2	(0.1)
Rheumatic Disorder	2	(0.1)	0		2	(0.1)
Seronegative Arthritis	1	(0.1)	1	(0.1)	2	(0.1)
Spinal Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Torticollis	0		2	(0.1)	2	(0.1)
Arthritis Reactive	1	(0.1)	0		1	(0.0)
Autoimmune Arthritis	1	(0.1)	0		1	(0.0)
Bone Cyst	0		1	(0.1)	1	(0.0)
Bone Disorder	1	(0.1)	0		1	(0.0)
Bone Loss	0		1	(0.1)	1	(0.0)
Bone Pain	1	(0.1)	0		1	(0.0)
Chondritis	0		1	(0.1)	1	(0.0)
Chondrocalcinosis Pyrophosphate	0		1	(0.1)	1	(0.0)
Degenerative Bone Disease	1	(0.1)	0		1	(0.0)
Discoid Meniscus	0		1	(0.1)	1	(0.0)
Fasciitis	1	(0.1)	0		1	(0.0)
Groin Pain	0		1	(0.1)	1	(0.0)
Intervertebral Disc Compression	0		1	(0.1)	1	(0.0)
Intervertebral Disc Space Narrowing	1	(0.1)	0		1	(0.0)
Jaw Cyst	1	(0.1)	0		1	(0.0)
Joint Effusion	0		1	(0.1)	1	(0.0)
Ligamentitis	0		1	(0.1)	1	(0.0)
Limb Discomfort	0		1	(0.1)	1	(0.0)
Medial Tibial Stress Syndrome	0		1	(0.1)	1	(0.0)
Muscle Tightness	0		1	(0.1)	1	(0.0)
Myosclerosis	1	(0.1)	0		1	(0.0)
Os Trigonum Syndrome	1	(0.1)	0		1	(0.0)
Osteitis Deformans	0		1	(0.1)	1	(0.0)
Osteoarthropathy	1	(0.1)	0		1	(0.0)
Osteonecrosis	0		1	(0.1)	1	(0.0)
Osteoporosis Postmenopausal	0		1	(0.1)	1	(0.0)
Osteosclerosis	1	(0.1)	0		1	(0.0)
Osteosis	0		1	(0.1)	1	(0.0)
Perthes Disease	1	(0.1)	0		1	(0.0)
Polymyositis	1	(0.1)	0		1	(0.0)
Posterior Tibial Tendon Dysfunction	0		1	(0.1)	1	(0.0)
Psoas Sign	0		1	(0.1)	1	(0.0)
Scleroderma	1	(0.1)	0		1	(0.0)
Somatic Dysfunction	0		1	(0.1)	1	(0.0)
Systemic Scleroderma	1	(0.1)	0		1	(0.0)
Tendon Pain	1	(0.1)	0		1	(0.0)
Vertebral Foraminal Stenosis	0		1	(0.1)	1	(0.0)
Vertebral Osteophyte	1	(0.1)	0		1	(0.0)
Gastrointestinal Disorders	577	(26.6)	638	(29.4)	1215	(28.0)
Gastrooesophageal Reflux Disease	249	(11.5)	275	(12.7)	524	(12.1)
Chronic Gastritis	76	(3.5)	92	(4.2)	168	(3.9)
Constipation	81	(3.7)	77	(3.5)	158	(3.6)
Gastritis	36	(1.7)	48	(2.2)	84	(1.9)
Haemorrhoids	40	(1.8)	40	(1.8)	80	(1.8)
Irritable Bowel Syndrome	35	(1.6)	39	(1.8)	74	(1.7)
Hiatus Hernia	30	(1.4)	34	(1.6)	64	(1.5)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Diverticulum	29	(1.3)	24	(1.1)	53	(1.2)
Dyspepsia	22	(1.0)	30	(1.4)	52	(1.2)
Large Intestine Polyp	18	(0.8)	24	(1.1)	42	(1.0)
Diarrhoea	26	(1.2)	14	(0.7)	40	(0.9)
Pancreatitis Chronic	18	(0.8)	22	(1.0)	40	(0.9)
Gastric Polyps	9	(0.4)	17	(0.8)	26	(0.6)
Diverticulum Intestinal	13	(0.6)	10	(0.5)	23	(0.5)
Umbilical Hernia	8	(0.4)	13	(0.6)	21	(0.5)
Colitis	10	(0.5)	8	(0.4)	18	(0.4)
Barrett's Oesophagus	7	(0.3)	9	(0.4)	16	(0.4)
Dental Caries	10	(0.5)	6	(0.3)	16	(0.4)
Duodenitis	7	(0.3)	7	(0.3)	14	(0.3)
Dysphagia	5	(0.2)	9	(0.4)	14	(0.3)
Gastric Ulcer	7	(0.3)	7	(0.3)	14	(0.3)
Peptic Ulcer	6	(0.3)	8	(0.4)	14	(0.3)
Colitis Ulcerative	2	(0.1)	10	(0.5)	12	(0.3)
Impaired Gastric Emptying	8	(0.4)	4	(0.2)	12	(0.3)
Crohn's Disease	6	(0.3)	5	(0.2)	11	(0.2)
Oesophagitis	7	(0.3)	4	(0.2)	11	(0.2)
Pancreatic Steatosis	4	(0.2)	7	(0.3)	11	(0.2)
Gastritis Erosive	6	(0.3)	4	(0.2)	10	(0.2)
Inguinal Hernia	3	(0.1)	7	(0.3)	10	(0.2)
Pancreatic Cyst	6	(0.3)	4	(0.2)	10	(0.2)
Periodontal Disease	5	(0.2)	5	(0.2)	10	(0.2)
Abdominal Hernia	4	(0.2)	5	(0.2)	9	(0.2)
Abdominal Pain	5	(0.2)	4	(0.2)	9	(0.2)
Abdominal Pain Upper	4	(0.2)	5	(0.2)	9	(0.2)
Duodenal Ulcer	2	(0.1)	7	(0.3)	9	(0.2)
Nausea	4	(0.2)	3	(0.1)	7	(0.2)
Reflux Gastritis	3	(0.1)	4	(0.2)	7	(0.2)
Abdominal Discomfort	3	(0.1)	3	(0.1)	6	(0.1)
Acquired Oesophageal Web	2	(0.1)	4	(0.2)	6	(0.1)
Coeliac Disease	2	(0.1)	3	(0.1)	5	(0.1)
Lumbar Hernia	0		5	(0.2)	5	(0.1)
Pancreatitis	4	(0.2)	1	(0.1)	5	(0.1)
Abdominal Distension	2	(0.1)	2	(0.1)	4	(0.1)
Duodenogastric Reflux	1	(0.1)	3	(0.1)	4	(0.1)
Gastrointestinal Disorder	1	(0.1)	3	(0.1)	4	(0.1)
Pancreatic Failure	3	(0.1)	1	(0.1)	4	(0.1)
Acid Peptic Disease	1	(0.1)	2	(0.1)	3	(0.1)
Anal Fissure	1	(0.1)	2	(0.1)	3	(0.1)
Erosive Duodenitis	0		3	(0.1)	3	(0.1)
Functional Gastrointestinal Disorder	1	(0.1)	2	(0.1)	3	(0.1)
Gastric Disorder	0		3	(0.1)	3	(0.1)
Oesophageal Polyp	1	(0.1)	2	(0.1)	3	(0.1)
Rectal Haemorrhage	2	(0.1)	1	(0.1)	3	(0.1)
Vomiting	1	(0.1)	2	(0.1)	3	(0.1)
Abdominal Pain Lower	0		2	(0.1)	2	(0.1)
Anal Incontinence	1	(0.1)	1	(0.1)	2	(0.1)
Diaphragmatic Hernia	0		2	(0.1)	2	(0.1)
Duodenal Bulb Deformity	1	(0.1)	1	(0.1)	2	(0.1)
Duodenal Polyp	1	(0.1)	1	(0.1)	2	(0.1)
Enterocolitis	1	(0.1)	1	(0.1)	2	(0.1)
Flatulence	2	(0.1)	0		2	(0.1)
Gastric Xanthoma	1	(0.1)	1	(0.1)	2	(0.1)
Gastrointestinal Wall Thickening	2	(0.1)	0		2	(0.1)
Gastrooesophageal Sphincter Insufficiency	1	(0.1)	1	(0.1)	2	(0.1)
Intestinal Polyp	1	(0.1)	1	(0.1)	2	(0.1)
Oesophageal Stenosis	0		2	(0.1)	2	(0.1)
Pancreatic Duct Dilatation	1	(0.1)	1	(0.1)	2	(0.1)
Pancreatic Mass	1	(0.1)	1	(0.1)	2	(0.1)
Poor Dental Condition	0		2	(0.1)	2	(0.1)
Rectal Fissure	0		2	(0.1)	2	(0.1)
Tooth Disorder	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Tooth Loss	0		2	(0.1)	2	(0.1)
Abdominal Adhesions	0		1	(0.1)	1	(0.0)
Abdominal Mass	0		1	(0.1)	1	(0.0)
Abdominal Tenderness	1	(0.1)	0		1	(0.0)
Anal Fistula	0		1	(0.1)	1	(0.0)
Anal Polyp	0		1	(0.1)	1	(0.0)
Anal Stenosis	0		1	(0.1)	1	(0.0)
Angular Cheilitis	1	(0.1)	0		1	(0.0)
Anorectal Varices	0		1	(0.1)	1	(0.0)
Apical Granuloma	0		1	(0.1)	1	(0.0)
Ascites	1	(0.1)	0		1	(0.0)
Colitis Microscopic	1	(0.1)	0		1	(0.0)
Defaecation Urgency	1	(0.1)	0		1	(0.0)
Diabetic Gastroparesis	1	(0.1)	0		1	(0.0)
Diabetic Gastropathy	0		1	(0.1)	1	(0.0)
Dry Mouth	0		1	(0.1)	1	(0.0)
Enterocele	0		1	(0.1)	1	(0.0)
Eosinophilic Oesophagitis	1	(0.1)	0		1	(0.0)
Erosive Oesophagitis	0		1	(0.1)	1	(0.0)
Gastric Mucosa Erythema	1	(0.1)	0		1	(0.0)
Gastrocoele	1	(0.1)	0		1	(0.0)
Gastrointestinal Erosion	1	(0.1)	0		1	(0.0)
Gastrointestinal Mucosa Hyperaemia	0		1	(0.1)	1	(0.0)
Gastrointestinal Polyp	1	(0.1)	0		1	(0.0)
Gastrointestinal Ulcer Haemorrhage	0		1	(0.1)	1	(0.0)
Gastrointestinal Vascular Malformation	0		1	(0.1)	1	(0.0)
Gastrolithiasis	0		1	(0.1)	1	(0.0)
Haemorrhagic Erosive Gastritis	0		1	(0.1)	1	(0.0)
Haemorrhoidal Haemorrhage	1	(0.1)	0		1	(0.0)
Hyperchlorhydria	0		1	(0.1)	1	(0.0)
Ileal Ulcer	1	(0.1)	0		1	(0.0)
Inflammatory Bowel Disease	1	(0.1)	0		1	(0.0)
Intestinal Mass	1	(0.1)	0		1	(0.0)
Intestinal Metaplasia	1	(0.1)	0		1	(0.0)
Large Intestinal Obstruction	1	(0.1)	0		1	(0.0)
Mesenteric Arteriosclerosis	1	(0.1)	0		1	(0.0)
Obstructive Pancreatitis	0		1	(0.1)	1	(0.0)
Oesophageal Achalasia	1	(0.1)	0		1	(0.0)
Pancreatic Enlargement	1	(0.1)	0		1	(0.0)
Pancreatic Pseudocyst	0		1	(0.1)	1	(0.0)
Pancreatolithiasis	0		1	(0.1)	1	(0.0)
Proctitis	0		1	(0.1)	1	(0.0)
Proctitis Ulcerative	0		1	(0.1)	1	(0.0)
Pseudodiverticular Disease	1	(0.1)	0		1	(0.0)
Rectal Polyp	1	(0.1)	0		1	(0.0)
Rectal Ulcer	1	(0.1)	0		1	(0.0)
Salivary Gland Calculus	1	(0.1)	0		1	(0.0)
Salivary Gland Cyst	0		1	(0.1)	1	(0.0)
Salivary Gland Pain	1	(0.1)	0		1	(0.0)
Stomatitis	1	(0.1)	0		1	(0.0)
Tooth Erosion	0		1	(0.1)	1	(0.0)
Tooth Impacted	1	(0.1)	0		1	(0.0)
Tooth Malformation	1	(0.1)	0		1	(0.0)
Toothache	0		1	(0.1)	1	(0.0)
Trichoglossia	1	(0.1)	0		1	(0.0)
Ulcerative Gastritis	1	(0.1)	0		1	(0.0)
Varices Oesophageal	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Renal And Urinary Disorders	482	(22.2)	495	(22.8)	977	(22.5)
Diabetic Nephropathy	232	(10.7)	221	(10.2)	453	(10.4)
Chronic Kidney Disease	97	(4.5)	117	(5.4)	214	(4.9)
Nephrolithiasis	67	(3.1)	67	(3.1)	134	(3.1)
Renal Cyst	59	(2.7)	62	(2.9)	121	(2.8)
Microalbuminuria	21	(1.0)	19	(0.9)	40	(0.9)
Calculus Urinary	22	(1.0)	16	(0.7)	38	(0.9)
Hypertonic Bladder	15	(0.7)	16	(0.7)	31	(0.7)
Nocturia	6	(0.3)	17	(0.8)	23	(0.5)
Urinary Incontinence	14	(0.7)	8	(0.4)	22	(0.5)
Pollakiuria	11	(0.5)	8	(0.4)	19	(0.4)
Proteinuria	9	(0.4)	8	(0.4)	17	(0.4)
Haematuria	11	(0.5)	4	(0.2)	15	(0.3)
Ureterolithiasis	4	(0.2)	8	(0.4)	12	(0.3)
Dysuria	4	(0.2)	6	(0.3)	10	(0.2)
Nephrocalcinosis	3	(0.1)	6	(0.3)	9	(0.2)
Stress Urinary Incontinence	2	(0.1)	5	(0.2)	7	(0.2)
Renal Failure	2	(0.1)	4	(0.2)	6	(0.1)
Hydronephrosis	3	(0.1)	2	(0.1)	5	(0.1)
Micturition Urgency	3	(0.1)	2	(0.1)	5	(0.1)
Nephropathy	0		5	(0.2)	5	(0.1)
Neurogenic Bladder	4	(0.2)	1	(0.1)	5	(0.1)
Lower Urinary Tract Symptoms	3	(0.1)	1	(0.1)	4	(0.1)
Renal Colic	2	(0.1)	2	(0.1)	4	(0.1)
Hypertensive Nephropathy	1	(0.1)	2	(0.1)	3	(0.1)
Renal Impairment	2	(0.1)	1	(0.1)	3	(0.1)
Renal Mass	1	(0.1)	2	(0.1)	3	(0.1)
Urge Incontinence	2	(0.1)	1	(0.1)	3	(0.1)
Albuminuria	1	(0.1)	1	(0.1)	2	(0.1)
Cystitis Interstitial	1	(0.1)	1	(0.1)	2	(0.1)
Nephroptosis	1	(0.1)	1	(0.1)	2	(0.1)
Polyuria	1	(0.1)	1	(0.1)	2	(0.1)
Renal Artery Stenosis	0		2	(0.1)	2	(0.1)
Renal Disorder	2	(0.1)	0		2	(0.1)
Urinary Tract Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Bladder Disorder	1	(0.1)	0		1	(0.0)
Bladder Dysfunction	1	(0.1)	0		1	(0.0)
Bladder Irritation	0		1	(0.1)	1	(0.0)
Bladder Prolapse	0		1	(0.1)	1	(0.0)
Bladder Stenosis	1	(0.1)	0		1	(0.0)
Calculus Bladder	0		1	(0.1)	1	(0.0)
Contracted Bladder	0		1	(0.1)	1	(0.0)
Glomerulonephritis Membranous	1	(0.1)	0		1	(0.0)
Glycosuria	0		1	(0.1)	1	(0.0)
Hydrocalyx	0		1	(0.1)	1	(0.0)
Incontinence	1	(0.1)	0		1	(0.0)
Kidney Fibrosis	0		1	(0.1)	1	(0.0)
Leukocyturia	0		1	(0.1)	1	(0.0)
Micturition Disorder	1	(0.1)	0		1	(0.0)
Nephrectasia	0		1	(0.1)	1	(0.0)
Nephropathy Toxic	0		1	(0.1)	1	(0.0)
Renal Aneurysm	0		1	(0.1)	1	(0.0)
Renal Artery Arteriosclerosis	1	(0.1)	0		1	(0.0)
Renal Tubular Necrosis	0		1	(0.1)	1	(0.0)
Single Functional Kidney	1	(0.1)	0		1	(0.0)
Tubulointerstitial Nephritis	1	(0.1)	0		1	(0.0)
Ureteric Stenosis	1	(0.1)	0		1	(0.0)
Urethral Stenosis	1	(0.1)	0		1	(0.0)
Urinary Retention	0		1	(0.1)	1	(0.0)
Urinary Tract Obstruction	0		1	(0.1)	1	(0.0)
Urine Flow Decreased	1	(0.1)	0		1	(0.0)
Vesicoureteric Reflux	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Cardiac Disorders	454	(20.9)	422	(19.4)	876	(20.2)
Coronary Artery Disease	206	(9.5)	175	(8.1)	381	(8.8)
Cardiac Failure	88	(4.1)	84	(3.9)	172	(4.0)
Atrial Fibrillation	63	(2.9)	40	(1.8)	103	(2.4)
Bundle Branch Block Right	33	(1.5)	26	(1.2)	59	(1.4)
Coronary Artery Stenosis	16	(0.7)	25	(1.1)	41	(0.9)
Bundle Branch Block Left	18	(0.8)	17	(0.8)	35	(0.8)
Myocardial Infarction	22	(1.0)	11	(0.5)	33	(0.8)
Angina Pectoris	14	(0.7)	18	(0.8)	32	(0.7)
Mitral Valve Incompetence	18	(0.8)	13	(0.6)	31	(0.7)
Left Ventricular Hypertrophy	20	(0.9)	8	(0.4)	28	(0.7)
Sinus Bradycardia	11	(0.5)	16	(0.7)	27	(0.6)
Ventricular Extrasystoles	13	(0.6)	14	(0.7)	27	(0.6)
Tachycardia	12	(0.6)	12	(0.6)	24	(0.6)
Arteriosclerosis Coronary Artery	8	(0.4)	15	(0.7)	23	(0.5)
Atrioventricular Block First Degree	13	(0.6)	10	(0.5)	23	(0.5)
Tricuspid Valve Incompetence	15	(0.7)	8	(0.4)	23	(0.5)
Supraventricular Extrasystoles	10	(0.5)	9	(0.4)	19	(0.4)
Sinus Tachycardia	8	(0.4)	10	(0.5)	18	(0.4)
Arrhythmia	9	(0.4)	8	(0.4)	17	(0.4)
Hypertensive Heart Disease	8	(0.4)	9	(0.4)	17	(0.4)
Palpitations	8	(0.4)	9	(0.4)	17	(0.4)
Myocardial Ischaemia	9	(0.4)	6	(0.3)	15	(0.3)
Bradycardia	5	(0.2)	6	(0.3)	11	(0.2)
Supraventricular Tachycardia	8	(0.4)	3	(0.1)	11	(0.2)
Cardiomegaly	3	(0.1)	6	(0.3)	9	(0.2)
Cardiomyopathy	3	(0.1)	6	(0.3)	9	(0.2)
Aortic Valve Incompetence	5	(0.2)	3	(0.1)	8	(0.2)
Left Ventricular Dysfunction	4	(0.2)	4	(0.2)	8	(0.2)
Sinus Arrhythmia	2	(0.1)	6	(0.3)	8	(0.2)
Cardiac Disorder	5	(0.2)	2	(0.1)	7	(0.2)
Angina Unstable	3	(0.1)	3	(0.1)	6	(0.1)
Atrioventricular Block	2	(0.1)	4	(0.2)	6	(0.1)
Ischaemic Cardiomyopathy	3	(0.1)	3	(0.1)	6	(0.1)
Left Atrial Enlargement	3	(0.1)	3	(0.1)	6	(0.1)
Aortic Valve Sclerosis	3	(0.1)	2	(0.1)	5	(0.1)
Aortic Valve Stenosis	1	(0.1)	4	(0.2)	5	(0.1)
Atrial Flutter	4	(0.2)	1	(0.1)	5	(0.1)
Cardiac Failure Congestive	5	(0.2)	0		5	(0.1)
Extrasystoles	2	(0.1)	3	(0.1)	5	(0.1)
Metabolic Cardiomyopathy	3	(0.1)	2	(0.1)	5	(0.1)
Myocardial Fibrosis	3	(0.1)	2	(0.1)	5	(0.1)
Diastolic Dysfunction	4	(0.2)	0		4	(0.1)
Heart Valve Incompetence	2	(0.1)	2	(0.1)	4	(0.1)
Sinus Node Dysfunction	2	(0.1)	2	(0.1)	4	(0.1)
Ventricular Tachycardia	2	(0.1)	2	(0.1)	4	(0.1)
Defect Conduction Intraventricular	2	(0.1)	1	(0.1)	3	(0.1)
Left Atrial Dilatation	2	(0.1)	1	(0.1)	3	(0.1)
Mitral Valve Prolapse	0		3	(0.1)	3	(0.1)
Pulmonary Valve Incompetence	2	(0.1)	1	(0.1)	3	(0.1)
Aortic Valve Calcification	2	(0.1)	0		2	(0.1)
Bundle Branch Block Bilateral	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac Failure Chronic	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac Ventricular Thrombosis	0		2	(0.1)	2	(0.1)
Cardiovascular Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Congestive Cardiomyopathy	0		2	(0.1)	2	(0.1)
Dilatation Atrial	2	(0.1)	0		2	(0.1)
Hypertensive Cardiomyopathy	0		2	(0.1)	2	(0.1)
Left Ventricular Failure	0		2	(0.1)	2	(0.1)
Mitral Valve Disease	0		2	(0.1)	2	(0.1)
Mitral Valve Stenosis	2	(0.1)	0		2	(0.1)
Tachyarrhythmia	2	(0.1)	0		2	(0.1)
Ventricular Arrhythmia	1	(0.1)	1	(0.1)	2	(0.1)
Aortic Valve Disease	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Arrhythmia Supraventricular	0		1	(0.1)	1	(0.0)
Atrial Enlargement	1	(0.1)	0		1	(0.0)
Atrial Tachycardia	1	(0.1)	0		1	(0.0)
Atrioventricular Block Second Degree	1	(0.1)	0		1	(0.0)
Bifascicular Block	1	(0.1)	0		1	(0.0)
Cardiac Hypertrophy	0		1	(0.1)	1	(0.0)
Cardiac Valve Disease	1	(0.1)	0		1	(0.0)
Chronic Left Ventricular Failure	0		1	(0.1)	1	(0.0)
Conduction Disorder	0		1	(0.1)	1	(0.0)
Coronary Artery Insufficiency	1	(0.1)	0		1	(0.0)
Gastrocardiac Syndrome	0		1	(0.1)	1	(0.0)
Left Ventricular Diastolic Collapse	1	(0.1)	0		1	(0.0)
Left Ventricular Dilatation	1	(0.1)	0		1	(0.0)
Left Ventricular Enlargement	0		1	(0.1)	1	(0.0)
Microvascular Coronary Artery Disease	1	(0.1)	0		1	(0.0)
Mitral Valve Sclerosis	0		1	(0.1)	1	(0.0)
Myocardial Necrosis	0		1	(0.1)	1	(0.0)
Nodal Rhythm	0		1	(0.1)	1	(0.0)
Postinfarction Angina	1	(0.1)	0		1	(0.0)
Prinzmetal Angina	0		1	(0.1)	1	(0.0)
Right Atrial Dilatation	1	(0.1)	0		1	(0.0)
Right Atrial Enlargement	1	(0.1)	0		1	(0.0)
Tricuspid Valve Disease	1	(0.1)	0		1	(0.0)
Ventricular Dysfunction	1	(0.1)	0		1	(0.0)
Ventricular Fibrillation	1	(0.1)	0		1	(0.0)
Ventricular Hypokinesia	1	(0.1)	0		1	(0.0)
Wolff-Parkinson-White Syndrome	1	(0.1)	0		1	(0.0)

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Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Hepatobiliary Disorders	401	(18.5)	437	(20.1)	838	(19.3)
Hepatic Steatosis	274	(12.6)	305	(14.1)	579	(13.3)
Cholelithiasis	51	(2.4)	62	(2.9)	113	(2.6)
Gallbladder Polyp	35	(1.6)	36	(1.7)	71	(1.6)
Nonalcoholic Fatty Liver Disease	25	(1.1)	18	(0.8)	43	(1.0)
Cholecystitis Chronic	14	(0.7)	26	(1.2)	40	(0.9)
Hepatic Cyst	14	(0.7)	18	(0.8)	32	(0.7)
Liver Disorder	20	(0.9)	12	(0.6)	32	(0.7)
Hepatomegaly	16	(0.7)	14	(0.7)	30	(0.7)
Hepatic Function Abnormal	7	(0.3)	18	(0.8)	25	(0.6)
Non-Alcoholic Steatohepatitis	9	(0.4)	13	(0.6)	22	(0.5)
Steatohepatitis	6	(0.3)	5	(0.2)	11	(0.2)
Cholecystitis	5	(0.2)	3	(0.1)	8	(0.2)
Hepatic Lesion	3	(0.1)	5	(0.2)	8	(0.2)
Alcoholic Liver Disease	4	(0.2)	3	(0.1)	7	(0.2)
Biliary Dyskinesia	3	(0.1)	4	(0.2)	7	(0.2)
Gallbladder Disorder	4	(0.2)	3	(0.1)	7	(0.2)
Hepatitis	1	(0.1)	5	(0.2)	6	(0.1)
Hyperplastic Cholecystopathy	1	(0.1)	5	(0.2)	6	(0.1)
Bile Duct Stone	4	(0.2)	1	(0.1)	5	(0.1)
Hepatic Cirrhosis	3	(0.1)	2	(0.1)	5	(0.1)
Chronic Hepatitis	2	(0.1)	2	(0.1)	4	(0.1)
Liver Injury	1	(0.1)	3	(0.1)	4	(0.1)
Hepatic Fibrosis	2	(0.1)	1	(0.1)	3	(0.1)
Hepatic Mass	2	(0.1)	1	(0.1)	3	(0.1)
Hyperbilirubinaemia	1	(0.1)	2	(0.1)	3	(0.1)
Autoimmune Hepatitis	1	(0.1)	1	(0.1)	2	(0.1)
Fatty Liver Alcoholic	0		2	(0.1)	2	(0.1)
Hepatic Calcification	1	(0.1)	1	(0.1)	2	(0.1)
Portal Hypertension	1	(0.1)	1	(0.1)	2	(0.1)
Sphincter Of Oddi Dysfunction	2	(0.1)	0		2	(0.1)
Biliary Dilatation	0		1	(0.1)	1	(0.0)
Biliary Tract Disorder	1	(0.1)	0		1	(0.0)
Cholestasis	0		1	(0.1)	1	(0.0)
Cirrhosis Alcoholic	0		1	(0.1)	1	(0.0)
Deficiency Of Bile Secretion	0		1	(0.1)	1	(0.0)
Diabetic Hepatopathy	0		1	(0.1)	1	(0.0)
Gallbladder Cholesterolosis	1	(0.1)	0		1	(0.0)
Post Cholecystectomy Syndrome	1	(0.1)	0		1	(0.0)
Primary Biliary Cholangitis	0		1	(0.1)	1	(0.0)
Respiratory, Thoracic And Mediastinal Disorders	399	(18.4)	408	(18.8)	807	(18.6)
Sleep Apnoea Syndrome	173	(8.0)	170	(7.8)	343	(7.9)
Asthma	103	(4.8)	115	(5.3)	218	(5.0)
Rhinitis Allergic	83	(3.8)	74	(3.4)	157	(3.6)
Chronic Obstructive Pulmonary Disease	48	(2.2)	47	(2.2)	95	(2.2)
Pulmonary Mass	16	(0.7)	19	(0.9)	35	(0.8)
Bronchitis Chronic	15	(0.7)	14	(0.7)	29	(0.7)
Cough	7	(0.3)	10	(0.5)	17	(0.4)
Dyspnoea	7	(0.3)	10	(0.5)	17	(0.4)
Emphysema	9	(0.4)	7	(0.3)	16	(0.4)
Nasal Septum Deviation	4	(0.2)	7	(0.3)	11	(0.2)
Dyspnoea Exertional	2	(0.1)	3	(0.1)	5	(0.1)
Nasal Congestion	0		5	(0.2)	5	(0.1)
Pulmonary Fibrosis	2	(0.1)	3	(0.1)	5	(0.1)
Asthma Exercise Induced	1	(0.1)	3	(0.1)	4	(0.1)
Bronchiectasis	2	(0.1)	2	(0.1)	4	(0.1)
Lung Opacity	1	(0.1)	3	(0.1)	4	(0.1)
Pulmonary Hypertension	4	(0.2)	0		4	(0.1)
Vasomotor Rhinitis	2	(0.1)	2	(0.1)	4	(0.1)
Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome	2	(0.1)	1	(0.1)	3	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Atelectasis	0		3	(0.1)	3	(0.1)
Bronchial Hyperreactivity	1	(0.1)	2	(0.1)	3	(0.1)
Cystic Lung Disease	1	(0.1)	2	(0.1)	3	(0.1)
Pulmonary Granuloma	0		3	(0.1)	3	(0.1)
Allergic Bronchitis	2	(0.1)	0		2	(0.1)
Cough Variant Asthma	0		2	(0.1)	2	(0.1)
Dysphonia	1	(0.1)	1	(0.1)	2	(0.1)
Epistaxis	1	(0.1)	1	(0.1)	2	(0.1)
Hypoxia	0		2	(0.1)	2	(0.1)
Nasal Dryness	1	(0.1)	1	(0.1)	2	(0.1)
Paranasal Cyst	1	(0.1)	1	(0.1)	2	(0.1)
Pleural Effusion	1	(0.1)	1	(0.1)	2	(0.1)
Reflux Laryngitis	2	(0.1)	0		2	(0.1)
Rhinorrhoea	1	(0.1)	1	(0.1)	2	(0.1)
Sinus Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Acute Respiratory Failure	1	(0.1)	0		1	(0.0)
Allergic Cough	0		1	(0.1)	1	(0.0)
Allergic Pharyngitis	1	(0.1)	0		1	(0.0)
Allergic Sinusitis	1	(0.1)	0		1	(0.0)
Apnoea	1	(0.1)	0		1	(0.0)
Bronchial Wall Thickening	1	(0.1)	0		1	(0.0)
Bronchospasm	0		1	(0.1)	1	(0.0)
Epiglottic Cyst	0		1	(0.1)	1	(0.0)
Laryngeal Disorder	0		1	(0.1)	1	(0.0)
Laryngeal Oedema	1	(0.1)	0		1	(0.0)
Lung Consolidation	1	(0.1)	0		1	(0.0)
Lung Disorder	1	(0.1)	0		1	(0.0)
Mediastinal Disorder	1	(0.1)	0		1	(0.0)
Nasal Obstruction	0		1	(0.1)	1	(0.0)
Nasal Polyps	1	(0.1)	0		1	(0.0)
Nasal Turbinate Hypertrophy	0		1	(0.1)	1	(0.0)
Obstructive Airways Disorder	0		1	(0.1)	1	(0.0)
Pharyngeal Polyp	0		1	(0.1)	1	(0.0)
Pleural Fibrosis	1	(0.1)	0		1	(0.0)
Pleural Thickening	0		1	(0.1)	1	(0.0)
Pneumonitis	0		1	(0.1)	1	(0.0)
Productive Cough	1	(0.1)	0		1	(0.0)
Pulmonary Embolism	1	(0.1)	0		1	(0.0)
Respiratory Distress	1	(0.1)	0		1	(0.0)
Respiratory Failure	1	(0.1)	0		1	(0.0)
Restrictive Pulmonary Disease	1	(0.1)	0		1	(0.0)
Rhinitis Perennial	1	(0.1)	0		1	(0.0)
Sinus Congestion	0		1	(0.1)	1	(0.0)
Snoring	1	(0.1)	0		1	(0.0)
Tracheal Scarring	1	(0.1)	0		1	(0.0)
Upper-Airway Cough Syndrome	0		1	(0.1)	1	(0.0)
Vocal Cord Cyst	1	(0.1)	0		1	(0.0)
Vocal Cord Thickening	0		1	(0.1)	1	(0.0)
Wheezing	1	(0.1)	0		1	(0.0)

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adsl.xpt; variable(s): NA; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHBODSYS MHDECOD; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y") & (CONTINFL == "Y" & MHLLT != "Type 1 diabetes mellitus" & MHLLT != "Type 2 diabetes mellitus")
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:07 - tmhconcomillscrsumsas/tmhconcomillscrsump3asas.txt

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Endocrine Disorders	377	(17.4)	402	(18.5)	779	(17.9)
Hypothyroidism	215	(9.9)	233	(10.7)	448	(10.3)
Goitre	68	(3.1)	80	(3.7)	148	(3.4)
Autoimmune Thyroiditis	34	(1.6)	44	(2.0)	78	(1.8)
Hypogonadism	30	(1.4)	15	(0.7)	45	(1.0)
Thyroid Mass	15	(0.7)	23	(1.1)	38	(0.9)
Hyperthyroidism	18	(0.8)	14	(0.7)	32	(0.7)
Testicular Failure	5	(0.2)	7	(0.3)	12	(0.3)
Basedow's Disease	7	(0.3)	2	(0.1)	9	(0.2)
Thyroid Cyst	5	(0.2)	3	(0.1)	8	(0.2)
Androgen Deficiency	2	(0.1)	4	(0.2)	6	(0.1)
Hyperparathyroidism Secondary	3	(0.1)	2	(0.1)	5	(0.1)
Hypogonadism Male	2	(0.1)	3	(0.1)	5	(0.1)
Primary Hypothyroidism	4	(0.2)	1	(0.1)	5	(0.1)
Secondary Hypogonadism	3	(0.1)	2	(0.1)	5	(0.1)
Adrenal Insufficiency	3	(0.1)	1	(0.1)	4	(0.1)
Thyroiditis Chronic	2	(0.1)	2	(0.1)	4	(0.1)
Adrenal Mass	1	(0.1)	1	(0.1)	2	(0.1)
Empty Sella Syndrome	1	(0.1)	1	(0.1)	2	(0.1)
Hyperandrogenism	0		2	(0.1)	2	(0.1)
Hyperparathyroidism	0		2	(0.1)	2	(0.1)
Hypoparathyroidism	0		2	(0.1)	2	(0.1)
Thyroid Calcification	1	(0.1)	1	(0.1)	2	(0.1)
Thyroiditis	1	(0.1)	1	(0.1)	2	(0.1)
Adrenal Disorder	0		1	(0.1)	1	(0.0)
Adrenocortical Insufficiency Acute	0		1	(0.1)	1	(0.0)
Adrenomegaly	0		1	(0.1)	1	(0.0)
Autoimmune Thyroid Disorder	1	(0.1)	0		1	(0.0)
Hyperprolactinaemia	1	(0.1)	0		1	(0.0)
Hypopituitarism	0		1	(0.1)	1	(0.0)
Oestrogen Deficiency	1	(0.1)	0		1	(0.0)
Polyglandular Disorder	0		1	(0.1)	1	(0.0)
Primary Hyperthyroidism	0		1	(0.1)	1	(0.0)
Primary Hypoparathyroidism	1	(0.1)	0		1	(0.0)
Thyroid Atrophy	1	(0.1)	0		1	(0.0)
Thyroid Disorder	0		1	(0.1)	1	(0.0)
Toxic Nodular Goitre	1	(0.1)	0		1	(0.0)
Virilism	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Psychiatric Disorders	368	(17.0)	352	(16.2)	720	(16.6)
Depression	188	(8.7)	167	(7.7)	355	(8.2)
Insomnia	98	(4.5)	96	(4.4)	194	(4.5)
Anxiety	90	(4.2)	97	(4.5)	187	(4.3)
Attention Deficit Hyperactivity Disorder	15	(0.7)	17	(0.8)	32	(0.7)
Anxiety Disorder	11	(0.5)	17	(0.8)	28	(0.7)
Major Depression	10	(0.5)	9	(0.4)	19	(0.4)
Generalised Anxiety Disorder	7	(0.3)	9	(0.4)	16	(0.4)
Bipolar Disorder	8	(0.4)	6	(0.3)	14	(0.3)
Tobacco Abuse	9	(0.4)	4	(0.2)	13	(0.3)
Post-Traumatic Stress Disorder	4	(0.2)	7	(0.3)	11	(0.2)
Nicotine Dependence	5	(0.2)	5	(0.2)	10	(0.2)
Sleep Disorder	6	(0.3)	3	(0.1)	9	(0.2)
Adjustment Disorder With Depressed Mood	4	(0.2)	3	(0.1)	7	(0.2)
Panic Attack	5	(0.2)	2	(0.1)	7	(0.2)
Persistent Depressive Disorder	1	(0.1)	5	(0.2)	6	(0.1)
Affective Disorder	3	(0.1)	2	(0.1)	5	(0.1)
Panic Disorder	4	(0.2)	1	(0.1)	5	(0.1)
Depressed Mood	2	(0.1)	1	(0.1)	3	(0.1)
Schizophrenia	1	(0.1)	2	(0.1)	3	(0.1)
Stress	1	(0.1)	2	(0.1)	3	(0.1)
Adjustment Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Alcohol Abuse	2	(0.1)	0		2	(0.1)
Bipolar Ii Disorder	2	(0.1)	0		2	(0.1)
Claustrophobia	1	(0.1)	1	(0.1)	2	(0.1)
Drug Dependence	1	(0.1)	1	(0.1)	2	(0.1)
Obsessive-Compulsive Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Psychotic Disorder	2	(0.1)	0		2	(0.1)
Acute Stress Disorder	0		1	(0.1)	1	(0.0)
Adjustment Disorder With Anxiety	1	(0.1)	0		1	(0.0)
Alcoholism	1	(0.1)	0		1	(0.0)
Binge Eating	1	(0.1)	0		1	(0.0)
Cardiovascular Somatic Symptom Disorder	0		1	(0.1)	1	(0.0)
Delusional Disorder, Unspecified Type	1	(0.1)	0		1	(0.0)
Libido Decreased	1	(0.1)	0		1	(0.0)
Mixed Anxiety And Depressive Disorder	0		1	(0.1)	1	(0.0)
Mood Altered	1	(0.1)	0		1	(0.0)
Neurosis	1	(0.1)	0		1	(0.0)
Parasomnia	1	(0.1)	0		1	(0.0)
Premature Ejaculation	0		1	(0.1)	1	(0.0)
Psychophysiologic Insomnia	0		1	(0.1)	1	(0.0)
Rapid Eye Movement Sleep Behaviour Disorder	0		1	(0.1)	1	(0.0)
Schizoaffective Disorder Depressive Type	0		1	(0.1)	1	(0.0)
Schizophreniform Disorder	1	(0.1)	0		1	(0.0)
Social Anxiety Disorder	1	(0.1)	0		1	(0.0)
Somatic Symptom Disorder	0		1	(0.1)	1	(0.0)
Tic	1	(0.1)	0		1	(0.0)
Reproductive System And Breast Disorders	305	(14.1)	301	(13.9)	606	(14.0)
Benign Prostatic Hyperplasia	123	(5.7)	115	(5.3)	238	(5.5)
Erectile Dysfunction	100	(4.6)	89	(4.1)	189	(4.3)
Prostatomegaly	9	(0.4)	16	(0.7)	25	(0.6)
Ovarian Cyst	10	(0.5)	12	(0.6)	22	(0.5)
Prostatitis	10	(0.5)	10	(0.5)	20	(0.5)
Menopausal Symptoms	11	(0.5)	8	(0.4)	19	(0.4)
Polycystic Ovaries	9	(0.4)	8	(0.4)	17	(0.4)
Atrophic Vulvovaginitis	6	(0.3)	10	(0.5)	16	(0.4)
Endometriosis	4	(0.2)	7	(0.3)	11	(0.2)
Fibrocystic Breast Disease	5	(0.2)	4	(0.2)	9	(0.2)
Breast Fibrosis	1	(0.1)	5	(0.2)	6	(0.1)
Calculus Prostatic	2	(0.1)	4	(0.2)	6	(0.1)
Breast Cyst	3	(0.1)	2	(0.1)	5	(0.1)
Breast Disorder	2	(0.1)	3	(0.1)	5	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Breast Hyperplasia	3	(0.1)	2	(0.1)	5	(0.1)
Dysmenorrhoea	4	(0.2)	1	(0.1)	5	(0.1)
Adenomyosis	0		4	(0.2)	4	(0.1)
Amenorrhoea	1	(0.1)	3	(0.1)	4	(0.1)
Breast Mass	2	(0.1)	2	(0.1)	4	(0.1)
Cervical Dysplasia	2	(0.1)	2	(0.1)	4	(0.1)
Cervix Disorder	1	(0.1)	3	(0.1)	4	(0.1)
Gynaecomastia	2	(0.1)	2	(0.1)	4	(0.1)
Uterine Polyp	3	(0.1)	1	(0.1)	4	(0.1)
Uterine Prolapse	3	(0.1)	1	(0.1)	4	(0.1)
Vulvovaginal Dryness	3	(0.1)	1	(0.1)	4	(0.1)
Breast Pain	2	(0.1)	1	(0.1)	3	(0.1)
Cervical Cyst	2	(0.1)	1	(0.1)	3	(0.1)
Heavy Menstrual Bleeding	2	(0.1)	1	(0.1)	3	(0.1)
Infertility	2	(0.1)	1	(0.1)	3	(0.1)
Prostatic Disorder	2	(0.1)	1	(0.1)	3	(0.1)
Breast Calcifications	0		2	(0.1)	2	(0.1)
Cystocele	1	(0.1)	1	(0.1)	2	(0.1)
Haematospermia	2	(0.1)	0		2	(0.1)
Infertility Male	1	(0.1)	1	(0.1)	2	(0.1)
Menstruation Irregular	1	(0.1)	1	(0.1)	2	(0.1)
Organic Erectile Dysfunction	0		2	(0.1)	2	(0.1)
Pelvic Adhesions	1	(0.1)	1	(0.1)	2	(0.1)
Peyronie's Disease	2	(0.1)	0		2	(0.1)
Premenstrual Syndrome	2	(0.1)	0		2	(0.1)
Prostatic Calcification	1	(0.1)	1	(0.1)	2	(0.1)
Vulvovaginal Discomfort	2	(0.1)	0		2	(0.1)
Artificial Menopause	1	(0.1)	0		1	(0.0)
Balanoposthitis	1	(0.1)	0		1	(0.0)
Breast Discharge	1	(0.1)	0		1	(0.0)
Breast Enlargement	1	(0.1)	0		1	(0.0)
Cervical Polyp	1	(0.1)	0		1	(0.0)
Ectropion Of Cervix	0		1	(0.1)	1	(0.0)
Endometrial Hyperplasia	0		1	(0.1)	1	(0.0)
Endometrial Thickening	0		1	(0.1)	1	(0.0)
Epididymal Cyst	0		1	(0.1)	1	(0.0)
Fallopian Tube Obstruction	1	(0.1)	0		1	(0.0)
Menopausal Disorder	0		1	(0.1)	1	(0.0)
Menstrual Disorder	1	(0.1)	0		1	(0.0)
Ovarian Mass	0		1	(0.1)	1	(0.0)
Pelvic Pain	1	(0.1)	0		1	(0.0)
Prostatic Cyst	0		1	(0.1)	1	(0.0)
Prostatic Mass	0		1	(0.1)	1	(0.0)
Prostatism	1	(0.1)	0		1	(0.0)
Pruritus Genital	1	(0.1)	0		1	(0.0)
Rectocele	1	(0.1)	0		1	(0.0)
Scrotal Inflammation	0		1	(0.1)	1	(0.0)
Testicular Atrophy	1	(0.1)	0		1	(0.0)
Testicular Cyst	0		1	(0.1)	1	(0.0)
Testicular Mass	1	(0.1)	0		1	(0.0)
Testicular Swelling	0		1	(0.1)	1	(0.0)
Uterine Cyst	0		1	(0.1)	1	(0.0)
Uterine Disorder	0		1	(0.1)	1	(0.0)
Uterovaginal Prolapse	0		1	(0.1)	1	(0.0)
Vaginal Haemorrhage	1	(0.1)	0		1	(0.0)
Vaginal Prolapse	1	(0.1)	0		1	(0.0)
Varicocele	0		1	(0.1)	1	(0.0)
Vulvovaginal Pruritus	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Immune System Disorders	272	(12.5)	274	(12.6)	546	(12.6)
Seasonal Allergy	151	(7.0)	168	(7.7)	319	(7.3)
Drug Hypersensitivity	78	(3.6)	87	(4.0)	165	(3.8)
Hypersensitivity	32	(1.5)	25	(1.1)	57	(1.3)
Food Allergy	16	(0.7)	14	(0.7)	30	(0.7)
Iodine Allergy	3	(0.1)	6	(0.3)	9	(0.2)
Multiple Allergies	7	(0.3)	2	(0.1)	9	(0.2)
Sarcoidosis	3	(0.1)	6	(0.3)	9	(0.2)
Rubber Sensitivity	5	(0.2)	3	(0.1)	8	(0.2)
Allergy To Metals	1	(0.1)	5	(0.2)	6	(0.1)
Allergy To Arthropod Bite	2	(0.1)	3	(0.1)	5	(0.1)
Allergy To Arthropod Sting	1	(0.1)	4	(0.2)	5	(0.1)
Anaphylactic Reaction	3	(0.1)	1	(0.1)	4	(0.1)
Dust Allergy	1	(0.1)	3	(0.1)	4	(0.1)
Allergy To Animal	1	(0.1)	2	(0.1)	3	(0.1)
Allergy To Vaccine	1	(0.1)	2	(0.1)	3	(0.1)
Contrast Media Allergy	0		3	(0.1)	3	(0.1)
Mite Allergy	0		3	(0.1)	3	(0.1)
Allergy To Chemicals	2	(0.1)	0		2	(0.1)
Allergy To Plants	0		2	(0.1)	2	(0.1)
Immunodeficiency Common Variable	1	(0.1)	0		1	(0.0)
Insulin Autoimmune Syndrome	0		1	(0.1)	1	(0.0)
Loefgren Syndrome	0		1	(0.1)	1	(0.0)
Milk Allergy	0		1	(0.1)	1	(0.0)
Mycotic Allergy	0		1	(0.1)	1	(0.0)
Perfume Sensitivity	0		1	(0.1)	1	(0.0)
Infections And Infestations	259	(11.9)	230	(10.6)	489	(11.3)
Onychomycosis	32	(1.5)	31	(1.4)	63	(1.4)
Pyelonephritis Chronic	24	(1.1)	29	(1.3)	53	(1.2)
Tinea Pedis	32	(1.5)	19	(0.9)	51	(1.2)
Sinusitis	18	(0.8)	13	(0.6)	31	(0.7)
Urinary Tract Infection	15	(0.7)	16	(0.7)	31	(0.7)
Dermatophytosis Of Nail	12	(0.6)	16	(0.7)	28	(0.7)
Rhinitis	9	(0.4)	11	(0.5)	20	(0.5)
Diverticulitis	11	(0.5)	7	(0.3)	18	(0.4)
Pharyngitis	7	(0.3)	9	(0.4)	16	(0.4)
Bronchitis	8	(0.4)	7	(0.3)	15	(0.3)
Cystitis	7	(0.3)	8	(0.4)	15	(0.3)
Chronic Sinusitis	7	(0.3)	5	(0.2)	12	(0.3)
Fungal Infection	7	(0.3)	5	(0.2)	12	(0.3)
Conjunctivitis	7	(0.3)	4	(0.2)	11	(0.2)
Vaginal Infection	5	(0.2)	5	(0.2)	10	(0.2)
Oral Herpes	5	(0.2)	4	(0.2)	9	(0.2)
Chronic Tonsillitis	6	(0.3)	2	(0.1)	8	(0.2)
Genital Herpes	5	(0.2)	3	(0.1)	8	(0.2)
Helicobacter Infection	4	(0.2)	4	(0.2)	8	(0.2)
Herpes Simplex	4	(0.2)	3	(0.1)	7	(0.2)
Hiv Infection	3	(0.1)	4	(0.2)	7	(0.2)
Hepatitis B	2	(0.1)	4	(0.2)	6	(0.1)
Otitis Media	5	(0.2)	1	(0.1)	6	(0.1)
Vulvovaginal Candidiasis	3	(0.1)	3	(0.1)	6	(0.1)
Chronic Hepatitis B	2	(0.1)	3	(0.1)	5	(0.1)
Hepatitis C	4	(0.2)	1	(0.1)	5	(0.1)
Laryngitis	1	(0.1)	4	(0.2)	5	(0.1)
Body Tinea	2	(0.1)	2	(0.1)	4	(0.1)
Cellulitis	3	(0.1)	1	(0.1)	4	(0.1)
Chronic Hepatitis C	3	(0.1)	1	(0.1)	4	(0.1)
Folliculitis	4	(0.2)	0		4	(0.1)
Gastroenteritis	2	(0.1)	2	(0.1)	4	(0.1)
Herpes Virus Infection	1	(0.1)	3	(0.1)	4	(0.1)
Herpes Zoster	1	(0.1)	3	(0.1)	4	(0.1)
Otitis Media Chronic	2	(0.1)	2	(0.1)	4	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Periodontitis	2	(0.1)	2	(0.1)	4	(0.1)
Tinea Versicolour	3	(0.1)	1	(0.1)	4	(0.1)
Fungal Skin Infection	1	(0.1)	2	(0.1)	3	(0.1)
Helicobacter Gastritis	2	(0.1)	1	(0.1)	3	(0.1)
Labyrinthitis	2	(0.1)	1	(0.1)	3	(0.1)
Otitis Externa	1	(0.1)	2	(0.1)	3	(0.1)
Viral Hepatitis Carrier	3	(0.1)	0		3	(0.1)
Vulvovaginal Mycotic Infection	1	(0.1)	2	(0.1)	3	(0.1)
Asymptomatic Bacteriuria	1	(0.1)	1	(0.1)	2	(0.1)
Candida Infection	1	(0.1)	1	(0.1)	2	(0.1)
Covid-19	2	(0.1)	0		2	(0.1)
Furuncle	1	(0.1)	1	(0.1)	2	(0.1)
Gastric Ulcer Helicobacter	1	(0.1)	1	(0.1)	2	(0.1)
Genital Herpes Simplex	2	(0.1)	0		2	(0.1)
Hepatitis Viral	1	(0.1)	1	(0.1)	2	(0.1)
Nasopharyngitis	1	(0.1)	1	(0.1)	2	(0.1)
Papilloma Viral Infection	1	(0.1)	1	(0.1)	2	(0.1)
Pilonidal Cyst	1	(0.1)	1	(0.1)	2	(0.1)
Pneumonia	1	(0.1)	1	(0.1)	2	(0.1)
Pyelonephritis	1	(0.1)	1	(0.1)	2	(0.1)
Salpingo-Oophoritis	2	(0.1)	0		2	(0.1)
Tinea Cruris	1	(0.1)	1	(0.1)	2	(0.1)
Tinea Infection	1	(0.1)	1	(0.1)	2	(0.1)
Tooth Abscess	0		2	(0.1)	2	(0.1)
Upper Respiratory Tract Infection	1	(0.1)	1	(0.1)	2	(0.1)
Abdominal Abscess	0		1	(0.1)	1	(0.0)
Acute Sinusitis	0		1	(0.1)	1	(0.0)
Aids Retinopathy	1	(0.1)	0		1	(0.0)
Anal Abscess	1	(0.1)	0		1	(0.0)
Anal Tinea	1	(0.1)	0		1	(0.0)
Arthritis Bacterial	0		1	(0.1)	1	(0.0)
Atypical Pneumonia	1	(0.1)	0		1	(0.0)
Bacterial Vaginosis	0		1	(0.1)	1	(0.0)
Balanitis Candida	0		1	(0.1)	1	(0.0)
Breast Abscess	1	(0.1)	0		1	(0.0)
Chorioretinitis	1	(0.1)	0		1	(0.0)
Dermatitis Infected	0		1	(0.1)	1	(0.0)
Dermatophytosis	1	(0.1)	0		1	(0.0)
Ear Infection	1	(0.1)	0		1	(0.0)
Ear Infection Fungal	1	(0.1)	0		1	(0.0)
Encephalitis	1	(0.1)	0		1	(0.0)
Endocarditis	0		1	(0.1)	1	(0.0)
Epididymitis	0		1	(0.1)	1	(0.0)
Erysipelas	0		1	(0.1)	1	(0.0)
Erythrasma	0		1	(0.1)	1	(0.0)
Genitourinary Tract Infection	1	(0.1)	0		1	(0.0)
Gingivitis	1	(0.1)	0		1	(0.0)
Hepatitis A	0		1	(0.1)	1	(0.0)
Hordeolum	0		1	(0.1)	1	(0.0)
Intervertebral Discitis	1	(0.1)	0		1	(0.0)
Lyme Disease	1	(0.1)	0		1	(0.0)
Mycobacterial Infection	1	(0.1)	0		1	(0.0)
Mycobacterium Avium Complex Infection	0		1	(0.1)	1	(0.0)
Oesophageal Candidiasis	1	(0.1)	0		1	(0.0)
Ophthalmic Herpes Zoster	1	(0.1)	0		1	(0.0)
Opisthorchiasis	0		1	(0.1)	1	(0.0)
Peritonitis	0		1	(0.1)	1	(0.0)
Post-Acute Covid-19 Syndrome	1	(0.1)	0		1	(0.0)
Staphylococcal Infection	1	(0.1)	0		1	(0.0)
Streptococcal Infection	1	(0.1)	0		1	(0.0)
Tonsillitis	0		1	(0.1)	1	(0.0)
Tooth Infection	1	(0.1)	0		1	(0.0)
Tornwaldt Bursitis	1	(0.1)	0		1	(0.0)
Tracheitis	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vestibular Neuronitis	0		1	(0.1)	1	(0.0)
Viral Upper Respiratory Tract Infection	0		1	(0.1)	1	(0.0)
Vulvitis	1	(0.1)	0		1	(0.0)
Skin And Subcutaneous Tissue Disorders	237	(10.9)	219	(10.1)	456	(10.5)
Psoriasis	39	(1.8)	36	(1.7)	75	(1.7)
Eczema	27	(1.2)	30	(1.4)	57	(1.3)
Hyperkeratosis	17	(0.8)	18	(0.8)	35	(0.8)
Dermatitis	15	(0.7)	12	(0.6)	27	(0.6)
Rosacea	9	(0.4)	12	(0.6)	21	(0.5)
Actinic Keratosis	12	(0.6)	4	(0.2)	16	(0.4)
Urticaria	8	(0.4)	7	(0.3)	15	(0.3)
Pruritus	9	(0.4)	5	(0.2)	14	(0.3)
Diabetic Foot	6	(0.3)	7	(0.3)	13	(0.3)
Seborrhoeic Dermatitis	12	(0.6)	1	(0.1)	13	(0.3)
Asteatosis	6	(0.3)	6	(0.3)	12	(0.3)
Vitiligo	8	(0.4)	4	(0.2)	12	(0.3)
Dermatitis Atopic	4	(0.2)	7	(0.3)	11	(0.2)
Acne	3	(0.1)	7	(0.3)	10	(0.2)
Ingrowing Nail	6	(0.3)	4	(0.2)	10	(0.2)
Rash	8	(0.4)	2	(0.1)	10	(0.2)
Dermatitis Contact	5	(0.2)	4	(0.2)	9	(0.2)
Dry Skin	6	(0.3)	3	(0.1)	9	(0.2)
Alopecia	5	(0.2)	3	(0.1)	8	(0.2)
Eczema Asteatotic	1	(0.1)	6	(0.3)	7	(0.2)
Skin Ulcer	5	(0.2)	2	(0.1)	7	(0.2)
Acanthosis Nigricans	3	(0.1)	3	(0.1)	6	(0.1)
Nail Dystrophy	2	(0.1)	3	(0.1)	5	(0.1)
Necrobiosis Lipoidica Diabeticorum	3	(0.1)	2	(0.1)	5	(0.1)
Solar Lentigo	2	(0.1)	3	(0.1)	5	(0.1)
Xeroderma	3	(0.1)	2	(0.1)	5	(0.1)
Androgenetic Alopecia	3	(0.1)	1	(0.1)	4	(0.1)
Dermatitis Allergic	2	(0.1)	2	(0.1)	4	(0.1)
Diabetic Dermopathy	1	(0.1)	3	(0.1)	4	(0.1)
Erythema	2	(0.1)	2	(0.1)	4	(0.1)
Hidradenitis	2	(0.1)	2	(0.1)	4	(0.1)
Hyperhidrosis	1	(0.1)	3	(0.1)	4	(0.1)
Intertrigo	3	(0.1)	1	(0.1)	4	(0.1)
Skin Lesion	1	(0.1)	3	(0.1)	4	(0.1)
Stasis Dermatitis	1	(0.1)	3	(0.1)	4	(0.1)
Granuloma Annulare	2	(0.1)	1	(0.1)	3	(0.1)
Hand Dermatitis	1	(0.1)	2	(0.1)	3	(0.1)
Keloid Scar	1	(0.1)	2	(0.1)	3	(0.1)
Neurodermatitis	1	(0.1)	2	(0.1)	3	(0.1)
Purpura Senile	3	(0.1)	0		3	(0.1)
Telangiectasia	2	(0.1)	1	(0.1)	3	(0.1)
Alopecia Areata	2	(0.1)	0		2	(0.1)
Cold Urticaria	1	(0.1)	1	(0.1)	2	(0.1)
Decubitus Ulcer	1	(0.1)	1	(0.1)	2	(0.1)
Dyshidrotic Eczema	1	(0.1)	1	(0.1)	2	(0.1)
Hirsutism	2	(0.1)	0		2	(0.1)
Lentigo	0		2	(0.1)	2	(0.1)
Lichen Planus	1	(0.1)	1	(0.1)	2	(0.1)
Lipodystrophy Acquired	0		2	(0.1)	2	(0.1)
Lipohypertrophy	1	(0.1)	1	(0.1)	2	(0.1)
Nail Hypertrophy	0		2	(0.1)	2	(0.1)
Night Sweats	2	(0.1)	0		2	(0.1)
Photosensitivity Reaction	1	(0.1)	1	(0.1)	2	(0.1)
Sensitive Skin	2	(0.1)	0		2	(0.1)
Skin Hypertrophy	1	(0.1)	1	(0.1)	2	(0.1)
Acquired Digital Fibrokeratoma	1	(0.1)	0		1	(0.0)
Alopecia Totalis	1	(0.1)	0		1	(0.0)
Angioedema	1	(0.1)	0		1	(0.0)
Cutaneous Vasculitis	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dermal Cyst	0		1	(0.1)	1	(0.0)
Diabetic Cheiroarthropathy	0		1	(0.1)	1	(0.0)
Drug Eruption	0		1	(0.1)	1	(0.0)
Eczema Nummular	0		1	(0.1)	1	(0.0)
Erythema Nodosum	0		1	(0.1)	1	(0.0)
Hair Disorder	1	(0.1)	0		1	(0.0)
Henoch-Schonlein Purpura	1	(0.1)	0		1	(0.0)
Ingrown Hair	0		1	(0.1)	1	(0.0)
Lichen Sclerosus	0		1	(0.1)	1	(0.0)
Lichen Striatus	0		1	(0.1)	1	(0.0)
Mechanical Urticaria	1	(0.1)	0		1	(0.0)
Milia	0		1	(0.1)	1	(0.0)
Miliaria	1	(0.1)	0		1	(0.0)
Nail Atrophy	1	(0.1)	0		1	(0.0)
Nail Bed Inflammation	1	(0.1)	0		1	(0.0)
Nail Discolouration	0		1	(0.1)	1	(0.0)
Nail Disorder	1	(0.1)	0		1	(0.0)
Nail Pigmentation	1	(0.1)	0		1	(0.0)
Nail Pitting	1	(0.1)	0		1	(0.0)
Neuropathic Ulcer	0		1	(0.1)	1	(0.0)
Onychogryphosis	1	(0.1)	0		1	(0.0)
Palmoplantar Pustulosis	1	(0.1)	0		1	(0.0)
Parakeratosis	0		1	(0.1)	1	(0.0)
Parapsoriasis	0		1	(0.1)	1	(0.0)
Pemphigus	0		1	(0.1)	1	(0.0)
Pigmentation Disorder	0		1	(0.1)	1	(0.0)
Precancerous Skin Lesion	0		1	(0.1)	1	(0.0)
Purpura	0		1	(0.1)	1	(0.0)
Rash Papular	0		1	(0.1)	1	(0.0)
Rash Pruritic	0		1	(0.1)	1	(0.0)
Skin Disorder	1	(0.1)	0		1	(0.0)
Skin Fibrosis	1	(0.1)	0		1	(0.0)
Skin Hyperpigmentation	1	(0.1)	0		1	(0.0)
Skin Hypopigmentation	0		1	(0.1)	1	(0.0)
Urticaria Cholinergic	1	(0.1)	0		1	(0.0)
Urticaria Chronic	0		1	(0.1)	1	(0.0)
Xanthelasma	0		1	(0.1)	1	(0.0)
Xanthoma	0		1	(0.1)	1	(0.0)
Social Circumstances	189	(8.7)	172	(7.9)	361	(8.3)
Menopause	101	(4.7)	85	(3.9)	186	(4.3)
Postmenopause	72	(3.3)	72	(3.3)	144	(3.3)
Tattoo	4	(0.2)	4	(0.2)	8	(0.2)
Cardiac Assistance Device User	4	(0.2)	1	(0.1)	5	(0.1)
Hearing Aid User	2	(0.1)	3	(0.1)	5	(0.1)
Tobacco User	3	(0.1)	1	(0.1)	4	(0.1)
Joint Prosthesis User	1	(0.1)	2	(0.1)	3	(0.1)
Corrective Lens User	2	(0.1)	0		2	(0.1)
Andropause	0		1	(0.1)	1	(0.0)
Denture Wearer	0		1	(0.1)	1	(0.0)
Ex-Tobacco User	0		1	(0.1)	1	(0.0)
Eye Prosthesis User	0		1	(0.1)	1	(0.0)
Homosexuality	0		1	(0.1)	1	(0.0)
Limb Prosthesis User	1	(0.1)	0		1	(0.0)
Organ Donor	1	(0.1)	0		1	(0.0)
Physical Abuse	1	(0.1)	0		1	(0.0)
Sexual Abuse	1	(0.1)	0		1	(0.0)
Wheelchair User	1	(0.1)	0		1	(0.0)
Investigations	140	(6.5)	139	(6.4)	279	(6.4)
Blood Cholesterol Increased	18	(0.8)	18	(0.8)	36	(0.8)
Cardiac Murmur	14	(0.7)	17	(0.8)	31	(0.7)
Blood Testosterone Decreased	5	(0.2)	10	(0.5)	15	(0.3)
Hepatic Enzyme Increased	7	(0.3)	8	(0.4)	15	(0.3)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. 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): NA; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHBODSYS MHDECOD; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y") & (CONTINFL == "Y" & MHLLT != "Type 1 diabetes mellitus" & MHLLT != "Type 2 diabetes mellitus")

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Liver Function Test Increased	11	(0.5)	2	(0.1)	13	(0.3)
Qrs Axis Abnormal	3	(0.1)	9	(0.4)	12	(0.3)
Blood Cholesterol	4	(0.2)	6	(0.3)	10	(0.2)
Blood Triglycerides Increased	5	(0.2)	5	(0.2)	10	(0.2)
Transaminases Increased	2	(0.1)	5	(0.2)	7	(0.2)
Prostatic Specific Antigen Increased	4	(0.2)	2	(0.1)	6	(0.1)
Alanine Aminotransferase Increased	2	(0.1)	3	(0.1)	5	(0.1)
Blood Alkaline Phosphatase Increased	5	(0.2)	0		5	(0.1)
Continuous Glucose Monitoring	1	(0.1)	4	(0.2)	5	(0.1)
Intraocular Pressure Increased	3	(0.1)	2	(0.1)	5	(0.1)
Blood Creatine Phosphokinase Increased	3	(0.1)	1	(0.1)	4	(0.1)
Carotid Bruit	3	(0.1)	1	(0.1)	4	(0.1)
Carotid Intima-Media Thickness Increased	3	(0.1)	1	(0.1)	4	(0.1)
Electrocardiogram Abnormal	1	(0.1)	3	(0.1)	4	(0.1)
Electrocardiogram St-T Change	3	(0.1)	1	(0.1)	4	(0.1)
Electrocardiogram T Wave Abnormal	3	(0.1)	1	(0.1)	4	(0.1)
Weight Increased	1	(0.1)	3	(0.1)	4	(0.1)
Amylase Increased	2	(0.1)	1	(0.1)	3	(0.1)
Arthroscopy	1	(0.1)	2	(0.1)	3	(0.1)
Blood Bilirubin Increased	2	(0.1)	1	(0.1)	3	(0.1)
Ejection Fraction	2	(0.1)	1	(0.1)	3	(0.1)
Liver Function Test Abnormal	1	(0.1)	2	(0.1)	3	(0.1)
Platelet Count Decreased	2	(0.1)	1	(0.1)	3	(0.1)
Vitamin D Decreased	1	(0.1)	2	(0.1)	3	(0.1)
Blood Creatinine Increased	0		2	(0.1)	2	(0.1)
Blood Pressure Increased	1	(0.1)	1	(0.1)	2	(0.1)
Blood Thyroid Stimulating Hormone Increased	0		2	(0.1)	2	(0.1)
Blood Triglycerides Abnormal	1	(0.1)	1	(0.1)	2	(0.1)
Blood Urea Increased	2	(0.1)	0		2	(0.1)
Body Mass Index Increased	2	(0.1)	0		2	(0.1)
Bone Density Decreased	1	(0.1)	1	(0.1)	2	(0.1)
Electrocardiogram Q Waves	1	(0.1)	1	(0.1)	2	(0.1)
Electrocardiogram Qrs Complex Abnormal	2	(0.1)	0		2	(0.1)
Electrocardiogram Qt Prolonged	0		2	(0.1)	2	(0.1)
Electrocardiogram Repolarisation Abnormality	0		2	(0.1)	2	(0.1)
Electrocardiogram T Wave Amplitude Decreased	0		2	(0.1)	2	(0.1)
Electrocardiogram T Wave Inversion	1	(0.1)	1	(0.1)	2	(0.1)
Haematocrit Increased	0		2	(0.1)	2	(0.1)
Hepatic Enzyme Abnormal	1	(0.1)	1	(0.1)	2	(0.1)
High Density Lipoprotein Decreased	0		2	(0.1)	2	(0.1)
Monocyte Count Decreased	0		2	(0.1)	2	(0.1)
Vitamin B12 Decreased	2	(0.1)	0		2	(0.1)
White Blood Cell Count Decreased	0		2	(0.1)	2	(0.1)
Abdominal Bruit	1	(0.1)	0		1	(0.0)
Acid Base Balance Abnormal	0		1	(0.1)	1	(0.0)
Androgens Decreased	1	(0.1)	0		1	(0.0)
Blood Bilirubin Decreased	1	(0.1)	0		1	(0.0)
Blood Creatinine Decreased	0		1	(0.1)	1	(0.0)
Blood Folate Decreased	0		1	(0.1)	1	(0.0)
Blood Potassium Increased	1	(0.1)	0		1	(0.0)
Blood Pressure Decreased	0		1	(0.1)	1	(0.0)
Blood Uric Acid Increased	0		1	(0.1)	1	(0.0)
Body Mass Index	0		1	(0.1)	1	(0.0)
Breath Sounds Abnormal	0		1	(0.1)	1	(0.0)
C-Reactive Protein Increased	1	(0.1)	0		1	(0.0)
Carbohydrate Antigen 19-9 Increased	0		1	(0.1)	1	(0.0)
Carcinoembryonic Antigen Increased	1	(0.1)	0		1	(0.0)
Colonoscopy	1	(0.1)	0		1	(0.0)
Corneal Reflex Decreased	1	(0.1)	0		1	(0.0)
Digestive Enzyme Abnormal	0		1	(0.1)	1	(0.0)
Ejection Fraction Decreased	1	(0.1)	0		1	(0.0)
Electrocardiogram Low Voltage	0		1	(0.1)	1	(0.0)
Electrocardiogram P Wave Abnormal	1	(0.1)	0		1	(0.0)
Electrocardiogram Q Wave Abnormal	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Electrocardiogram St Segment Abnormal	0		1	(0.1)	1	(0.0)
Electrocardiogram St Segment Depression	0		1	(0.1)	1	(0.0)
Electrocardiogram St Segment Elevation	0		1	(0.1)	1	(0.0)
Electrocardiogram St-T Segment Abnormal	1	(0.1)	0		1	(0.0)
Enzyme Activity Increased	1	(0.1)	0		1	(0.0)
False Positive Investigation Result	1	(0.1)	0		1	(0.0)
Femoral Bruit	1	(0.1)	0		1	(0.0)
Glomerular Filtration Rate Decreased	0		1	(0.1)	1	(0.0)
Granulocyte Count Decreased	0		1	(0.1)	1	(0.0)
Heart Rate Irregular	1	(0.1)	0		1	(0.0)
Hepatitis B Core Antibody Positive	1	(0.1)	0		1	(0.0)
Hepatitis B Surface Antigen Positive	1	(0.1)	0		1	(0.0)
Hepatitis B Virus Test Positive	1	(0.1)	0		1	(0.0)
Hla-B*27 Positive	0		1	(0.1)	1	(0.0)
Hormone Level Abnormal	1	(0.1)	0		1	(0.0)
Lipase Increased	1	(0.1)	0		1	(0.0)
Lipoprotein (A) Increased	0		1	(0.1)	1	(0.0)
Low Density Lipoprotein Increased	1	(0.1)	0		1	(0.0)
Mammogram Abnormal	0		1	(0.1)	1	(0.0)
Monocyte Percentage Decreased	0		1	(0.1)	1	(0.0)
Mononuclear Cell Count Decreased	1	(0.1)	0		1	(0.0)
Mycobacterium Tuberculosis Complex Test Positive	0		1	(0.1)	1	(0.0)
Neutrophil Count Decreased	0		1	(0.1)	1	(0.0)
Neutrophil Count Increased	1	(0.1)	0		1	(0.0)
Nutritional Condition Abnormal	0		1	(0.1)	1	(0.0)
Occult Blood Positive	1	(0.1)	0		1	(0.0)
Oestradiol Increased	0		1	(0.1)	1	(0.0)
Pancreatic Enzymes Increased	1	(0.1)	0		1	(0.0)
Pedal Pulse Abnormal	0		1	(0.1)	1	(0.0)
Progesterone Decreased	1	(0.1)	0		1	(0.0)
Pulse Abnormal	1	(0.1)	0		1	(0.0)
Red Blood Cell Count Decreased	1	(0.1)	0		1	(0.0)
Red Blood Cell Count Increased	1	(0.1)	0		1	(0.0)
Red Blood Cell Sedimentation Rate Increased	1	(0.1)	0		1	(0.0)
Renal Function Test Abnormal	1	(0.1)	0		1	(0.0)
Sensory Level Abnormal	1	(0.1)	0		1	(0.0)
Serum Ferritin Decreased	1	(0.1)	0		1	(0.0)
Sinus Rhythm	1	(0.1)	0		1	(0.0)
Thyroid Function Test Abnormal	1	(0.1)	0		1	(0.0)
Tuberculin Test Positive	1	(0.1)	0		1	(0.0)
Urine Albumin/Creatinine Ratio Increased	1	(0.1)	0		1	(0.0)
Urine Uric Acid Increased	1	(0.1)	0		1	(0.0)
Visual Acuity Tests	0		1	(0.1)	1	(0.0)
Vitamin B12	1	(0.1)	0		1	(0.0)
Vitamin D	0		1	(0.1)	1	(0.0)
Surgical And Medical Procedures	145	(6.7)	121	(5.6)	266	(6.1)
Intraocular Lens Implant	16	(0.7)	15	(0.7)	31	(0.7)
Percutaneous Coronary Intervention	14	(0.7)	17	(0.8)	31	(0.7)
Hysterectomy	12	(0.6)	9	(0.4)	21	(0.5)
Female Sterilisation	11	(0.5)	9	(0.4)	20	(0.5)
Coronary Artery Bypass	12	(0.6)	7	(0.3)	19	(0.4)
Cardiac Pacemaker Insertion	7	(0.3)	2	(0.1)	9	(0.2)
Knee Arthroplasty	4	(0.2)	4	(0.2)	8	(0.2)
Peripheral Revascularisation	4	(0.2)	4	(0.2)	8	(0.2)
Cholecystectomy	6	(0.3)	1	(0.1)	7	(0.2)
Positive Airway Pressure Therapy	4	(0.2)	2	(0.1)	6	(0.1)
Aortic Valve Replacement	2	(0.1)	3	(0.1)	5	(0.1)
Appendicectomy	3	(0.1)	2	(0.1)	5	(0.1)
Leg Amputation	4	(0.2)	1	(0.1)	5	(0.1)
Thyroidectomy	4	(0.2)	1	(0.1)	5	(0.1)
Tonsillectomy	3	(0.1)	2	(0.1)	5	(0.1)
Implantable Defibrillator Insertion	1	(0.1)	3	(0.1)	4	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Retinal Laser Coagulation	1	(0.1)	3	(0.1)	4	(0.1)
Vitrectomy	2	(0.1)	2	(0.1)	4	(0.1)
Cataract Operation	2	(0.1)	1	(0.1)	3	(0.1)
Contraception	2	(0.1)	1	(0.1)	3	(0.1)
Hip Arthroplasty	2	(0.1)	1	(0.1)	3	(0.1)
Inguinal Hernia Repair	2	(0.1)	1	(0.1)	3	(0.1)
Knee Operation	2	(0.1)	1	(0.1)	3	(0.1)
Prophylaxis	1	(0.1)	2	(0.1)	3	(0.1)
Spinal Fusion Surgery	3	(0.1)	0		3	(0.1)
Vasectomy	2	(0.1)	1	(0.1)	3	(0.1)
Adenoidectomy	0		2	(0.1)	2	(0.1)
Cardiac Resynchronisation Therapy	1	(0.1)	1	(0.1)	2	(0.1)
Carotid Revascularisation	1	(0.1)	1	(0.1)	2	(0.1)
Coronary Arterial Stent Insertion	1	(0.1)	1	(0.1)	2	(0.1)
Dental Implantation	1	(0.1)	1	(0.1)	2	(0.1)
Gastrectomy	0		2	(0.1)	2	(0.1)
Hernia Repair	0		2	(0.1)	2	(0.1)
Hysterosalpingo-Oophorectomy	2	(0.1)	0		2	(0.1)
Intrauterine Contraception	1	(0.1)	1	(0.1)	2	(0.1)
Large Intestinal Polypectomy	0		2	(0.1)	2	(0.1)
Lithotripsy	1	(0.1)	1	(0.1)	2	(0.1)
Meniscus Removal	0		2	(0.1)	2	(0.1)
Spinal Nerve Stimulator Implantation	0		2	(0.1)	2	(0.1)
Toe Amputation	0		2	(0.1)	2	(0.1)
Anticoagulant Therapy	0		1	(0.1)	1	(0.0)
Arteriovenous Fistula Operation	0		1	(0.1)	1	(0.0)
Brain Stent Insertion	1	(0.1)	0		1	(0.0)
Breast Conserving Surgery	0		1	(0.1)	1	(0.0)
Breast Reconstruction	1	(0.1)	0		1	(0.0)
Cardioversion	0		1	(0.1)	1	(0.0)
Carotid Artery Stent Insertion	0		1	(0.1)	1	(0.0)
Catheter Placement	0		1	(0.1)	1	(0.0)
Choledocholithotomy	1	(0.1)	0		1	(0.0)
Circumcision	0		1	(0.1)	1	(0.0)
Cochlea Implant	1	(0.1)	0		1	(0.0)
Colectomy	1	(0.1)	0		1	(0.0)
Compression Garment Application	0		1	(0.1)	1	(0.0)
Covid-19 Immunisation	1	(0.1)	0		1	(0.0)
Ear Tube Insertion	0		1	(0.1)	1	(0.0)
Eye Prosthesis Insertion	1	(0.1)	0		1	(0.0)
Eye Prosthesis Removal	1	(0.1)	0		1	(0.0)
Finger Amputation	1	(0.1)	0		1	(0.0)
Foot Operation	1	(0.1)	0		1	(0.0)
Gastric Banding	1	(0.1)	0		1	(0.0)
Glaucoma Surgery	0		1	(0.1)	1	(0.0)
Heart Valve Replacement	1	(0.1)	0		1	(0.0)
Hip Surgery	0		1	(0.1)	1	(0.0)
Hysterotomy	1	(0.1)	0		1	(0.0)
Intervertebral Disc Operation	0		1	(0.1)	1	(0.0)
Keratomileusis	1	(0.1)	0		1	(0.0)
Laser Therapy	1	(0.1)	0		1	(0.0)
Liver Transplant	1	(0.1)	0		1	(0.0)
Mass Excision	0		1	(0.1)	1	(0.0)
Meniscus Operation	1	(0.1)	0		1	(0.0)
Mitral Valve Replacement	1	(0.1)	0		1	(0.0)
Nephrectomy	0		1	(0.1)	1	(0.0)
Oophorectomy	1	(0.1)	0		1	(0.0)
Oophorectomy Bilateral	1	(0.1)	0		1	(0.0)
Ovarian Cystectomy	1	(0.1)	0		1	(0.0)
Polypectomy	0		1	(0.1)	1	(0.0)
Rectal Polypectomy	0		1	(0.1)	1	(0.0)
Renal Transplant	1	(0.1)	0		1	(0.0)
Routine Health Maintenance	1	(0.1)	0		1	(0.0)
Scleral Operation	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Sinus Operation	0		1	(0.1)	1	(0.0)
Spinal Decompression	1	(0.1)	0		1	(0.0)
Thrombosis Prophylaxis	0		1	(0.1)	1	(0.0)
Tooth Restoration	0		1	(0.1)	1	(0.0)
Transurethral Bladder Resection	1	(0.1)	0		1	(0.0)
Transurethral Prostatectomy	0		1	(0.1)	1	(0.0)
Urinary Bladder Suspension	0		1	(0.1)	1	(0.0)
Varicocele Repair	0		1	(0.1)	1	(0.0)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	134	(6.2)	130	(6.0)	264	(6.1)
Uterine Leiomyoma	24	(1.1)	20	(0.9)	44	(1.0)
Benign Neoplasm Of Thyroid Gland	16	(0.7)	13	(0.6)	29	(0.7)
Haemangioma Of Liver	8	(0.4)	16	(0.7)	24	(0.6)
Fibroadenoma Of Breast	8	(0.4)	8	(0.4)	16	(0.4)
Seborrhoeic Keratosis	7	(0.3)	9	(0.4)	16	(0.4)
Lipoma	8	(0.4)	7	(0.3)	15	(0.3)
Melanocytic Naevus	9	(0.4)	4	(0.2)	13	(0.3)
Eye Naevus	3	(0.1)	7	(0.3)	10	(0.2)
Prostatic Adenoma	5	(0.2)	4	(0.2)	9	(0.2)
Acrochordon	5	(0.2)	2	(0.1)	7	(0.2)
Adrenal Adenoma	2	(0.1)	4	(0.2)	6	(0.1)
Gastrointestinal Tract Adenoma	4	(0.2)	2	(0.1)	6	(0.1)
Intraductal Papillary Mucinous Neoplasm	3	(0.1)	3	(0.1)	6	(0.1)
Colon Adenoma	2	(0.1)	3	(0.1)	5	(0.1)
Skin Papilloma	3	(0.1)	2	(0.1)	5	(0.1)
Basal Cell Carcinoma	3	(0.1)	1	(0.1)	4	(0.1)
Meningioma	0		4	(0.2)	4	(0.1)
Renal Hamartoma	2	(0.1)	2	(0.1)	4	(0.1)
Benign Breast Neoplasm	1	(0.1)	2	(0.1)	3	(0.1)
Breast Cancer	1	(0.1)	2	(0.1)	3	(0.1)
Haemangioma Of Bone	1	(0.1)	2	(0.1)	3	(0.1)
Haemangioma Of Skin	2	(0.1)	1	(0.1)	3	(0.1)
Adenoma Benign	2	(0.1)	0		2	(0.1)
Adrenal Neoplasm	1	(0.1)	1	(0.1)	2	(0.1)
Angiomyolipoma	1	(0.1)	1	(0.1)	2	(0.1)
Benign Lung Neoplasm	0		2	(0.1)	2	(0.1)
Benign Neoplasm Of Choroid	0		2	(0.1)	2	(0.1)
Benign Neoplasm Of Skin	1	(0.1)	1	(0.1)	2	(0.1)
Breast Neoplasm	1	(0.1)	1	(0.1)	2	(0.1)
Haemangioma	1	(0.1)	1	(0.1)	2	(0.1)
Lipoma Of Breast	1	(0.1)	1	(0.1)	2	(0.1)
Neoplasm Skin	1	(0.1)	1	(0.1)	2	(0.1)
Polycythaemia Vera	2	(0.1)	0		2	(0.1)
Angiolipoma	0		1	(0.1)	1	(0.0)
Anogenital Warts	1	(0.1)	0		1	(0.0)
Benign Bone Neoplasm	0		1	(0.1)	1	(0.0)
Benign Lymph Node Neoplasm	1	(0.1)	0		1	(0.0)
Benign Neoplasm	1	(0.1)	0		1	(0.0)
Benign Neoplasm Of Adrenal Gland	1	(0.1)	0		1	(0.0)
Benign Neoplasm Of Cervix Uteri	1	(0.1)	0		1	(0.0)
Benign Neoplasm Of Spinal Cord	1	(0.1)	0		1	(0.0)
Benign Renal Neoplasm	1	(0.1)	0		1	(0.0)
Benign Salivary Gland Neoplasm	0		1	(0.1)	1	(0.0)
Benign Soft Tissue Neoplasm	1	(0.1)	0		1	(0.0)
Benign Vascular Neoplasm	0		1	(0.1)	1	(0.0)
Bladder Cancer	1	(0.1)	0		1	(0.0)
Blepharal Papilloma	0		1	(0.1)	1	(0.0)
Carcinoid Tumour Of The Stomach	1	(0.1)	0		1	(0.0)
Cholesteatoma	1	(0.1)	0		1	(0.0)
Gallbladder Neoplasm	1	(0.1)	0		1	(0.0)
Gastrointestinal Submucosal Tumour	0		1	(0.1)	1	(0.0)
Haemangioma Of Spleen	0		1	(0.1)	1	(0.0)
Intra-Abdominal Haemangioma	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Langerhans' Cell Histiocytosis	1	(0.1)	0		1	(0.0)
Leiomyoma	0		1	(0.1)	1	(0.0)
Lymphangioma	0		1	(0.1)	1	(0.0)
Meningeal Neoplasm	0		1	(0.1)	1	(0.0)
Meningioma Benign	0		1	(0.1)	1	(0.0)
Myelodysplastic Syndrome	0		1	(0.1)	1	(0.0)
Myelolipoma	0		1	(0.1)	1	(0.0)
Neuroendocrine Tumour	1	(0.1)	0		1	(0.0)
Neurofibroma	1	(0.1)	0		1	(0.0)
Non-Hodgkin's Lymphoma	1	(0.1)	0		1	(0.0)
Non-Secretory Adenoma Of Pituitary	1	(0.1)	0		1	(0.0)
Pituitary Tumour	0		1	(0.1)	1	(0.0)
Pituitary Tumour Benign	0		1	(0.1)	1	(0.0)
Prostate Cancer	0		1	(0.1)	1	(0.0)
Prostate Cancer Stage I	0		1	(0.1)	1	(0.0)
Skin Cancer	0		1	(0.1)	1	(0.0)
Systemic Mastocytosis	1	(0.1)	0		1	(0.0)
Thyroid Adenoma	1	(0.1)	0		1	(0.0)
Thyroid Neoplasm	1	(0.1)	0		1	(0.0)
General Disorders And Administration Site Conditions	118	(5.4)	103	(4.8)	221	(5.1)
Fatigue	34	(1.6)	21	(1.0)	55	(1.3)
Drug Intolerance	15	(0.7)	18	(0.8)	33	(0.8)
Oedema Peripheral	14	(0.7)	17	(0.8)	31	(0.7)
Pain	12	(0.6)	11	(0.5)	23	(0.5)
Asthenia	9	(0.4)	11	(0.5)	20	(0.5)
Oedema	9	(0.4)	10	(0.5)	19	(0.4)
Malaise	10	(0.5)	5	(0.2)	15	(0.3)
Chest Pain	7	(0.3)	2	(0.1)	9	(0.2)
Gait Disturbance	5	(0.2)	2	(0.1)	7	(0.2)
Cyst	0		5	(0.2)	5	(0.1)
Hernia	2	(0.1)	2	(0.1)	4	(0.1)
Hypertrophy	3	(0.1)	1	(0.1)	4	(0.1)
Peripheral Swelling	2	(0.1)	2	(0.1)	4	(0.1)
Nodule	1	(0.1)	2	(0.1)	3	(0.1)
Lithiasis	0		2	(0.1)	2	(0.1)
Mass	1	(0.1)	1	(0.1)	2	(0.1)
Oedema Due To Renal Disease	2	(0.1)	0		2	(0.1)
Thirst	2	(0.1)	0		2	(0.1)
Calcinosis	1	(0.1)	0		1	(0.0)
Chest Discomfort	1	(0.1)	0		1	(0.0)
Chronic Fatigue Syndrome	0		1	(0.1)	1	(0.0)
Dysplasia	0		1	(0.1)	1	(0.0)
Facial Pain	0		1	(0.1)	1	(0.0)
Fat Tissue Increased	1	(0.1)	0		1	(0.0)
Fibrosis	0		1	(0.1)	1	(0.0)
Ill-Defined Disorder	0		1	(0.1)	1	(0.0)
Impaired Healing	1	(0.1)	0		1	(0.0)
Injection Site Induration	1	(0.1)	0		1	(0.0)
Medical Device Pain	0		1	(0.1)	1	(0.0)
Necrosis	1	(0.1)	0		1	(0.0)
Polyp	1	(0.1)	0		1	(0.0)
Pseudocyst	0		1	(0.1)	1	(0.0)
Sense Of Oppression	0		1	(0.1)	1	(0.0)
Stenosis	0		1	(0.1)	1	(0.0)
Temperature Intolerance	1	(0.1)	0		1	(0.0)
Tenderness	1	(0.1)	0		1	(0.0)
Ulcer	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Blood And Lymphatic System Disorders	111	(5.1)	101	(4.7)	212	(4.9)
Anaemia	54	(2.5)	42	(1.9)	96	(2.2)
Iron Deficiency Anaemia	22	(1.0)	26	(1.2)	48	(1.1)
Polycythaemia	8	(0.4)	6	(0.3)	14	(0.3)
Thrombocytopenia	9	(0.4)	3	(0.1)	12	(0.3)
Leukocytosis	3	(0.1)	4	(0.2)	7	(0.2)
Splenomegaly	3	(0.1)	4	(0.2)	7	(0.2)
Anaemia Vitamin B12 Deficiency	1	(0.1)	3	(0.1)	4	(0.1)
Thrombocytosis	3	(0.1)	1	(0.1)	4	(0.1)
Lymphadenopathy	2	(0.1)	1	(0.1)	3	(0.1)
Microcytic Anaemia	3	(0.1)	0		3	(0.1)
Microcytosis	3	(0.1)	0		3	(0.1)
Normochromic Anaemia	1	(0.1)	2	(0.1)	3	(0.1)
Leukopenia	1	(0.1)	1	(0.1)	2	(0.1)
Normocytic Anaemia	1	(0.1)	1	(0.1)	2	(0.1)
Anaemia Macrocytic	1	(0.1)	0		1	(0.0)
Antiphospholipid Syndrome	0		1	(0.1)	1	(0.0)
Deficiency Anaemia	1	(0.1)	0		1	(0.0)
Elephantiasis	0		1	(0.1)	1	(0.0)
Eosinophilia	0		1	(0.1)	1	(0.0)
Haemolytic Anaemia	0		1	(0.1)	1	(0.0)
Hypercoagulation	0		1	(0.1)	1	(0.0)
Hyperglobulinaemia	0		1	(0.1)	1	(0.0)
Hypochromic Anaemia	1	(0.1)	0		1	(0.0)
Immune Thrombocytopenia	0		1	(0.1)	1	(0.0)
Increased Tendency To Bruise	1	(0.1)	0		1	(0.0)
Macrocytosis	0		1	(0.1)	1	(0.0)
Nephrogenic Anaemia	1	(0.1)	0		1	(0.0)
Normochromic Normocytic Anaemia	1	(0.1)	0		1	(0.0)
Pancytopenia	1	(0.1)	0		1	(0.0)
Paratracheal Lymphadenopathy	0		1	(0.1)	1	(0.0)
Pernicious Anaemia	0		1	(0.1)	1	(0.0)
Ear And Labyrinth Disorders	84	(3.9)	83	(3.8)	167	(3.9)
Tinnitus	11	(0.5)	13	(0.6)	24	(0.6)
Deafness	11	(0.5)	12	(0.6)	23	(0.5)
Vertigo	15	(0.7)	8	(0.4)	23	(0.5)
Deafness Bilateral	11	(0.5)	7	(0.3)	18	(0.4)
Hypoacusis	11	(0.5)	7	(0.3)	18	(0.4)
Vertigo Positional	7	(0.3)	8	(0.4)	15	(0.3)
Deafness Neurosensory	3	(0.1)	9	(0.4)	12	(0.3)
Meniere's Disease	6	(0.3)	6	(0.3)	12	(0.3)
Deafness Unilateral	6	(0.3)	5	(0.2)	11	(0.2)
Eustachian Tube Dysfunction	1	(0.1)	2	(0.1)	3	(0.1)
Sudden Hearing Loss	2	(0.1)	1	(0.1)	3	(0.1)
Vestibular Ataxia	1	(0.1)	2	(0.1)	3	(0.1)
Cerumen Impaction	0		2	(0.1)	2	(0.1)
Tympanic Membrane Perforation	1	(0.1)	1	(0.1)	2	(0.1)
Conductive Deafness	1	(0.1)	0		1	(0.0)
Ear Pain	0		1	(0.1)	1	(0.0)
Eustachian Tube Disorder	1	(0.1)	0		1	(0.0)
Hyperacusis	0		1	(0.1)	1	(0.0)
Inner Ear Disorder	1	(0.1)	0		1	(0.0)
Motion Sickness	0		1	(0.1)	1	(0.0)
Presbyacusis	0		1	(0.1)	1	(0.0)
Tympanic Membrane Disorder	0		1	(0.1)	1	(0.0)
Vestibular Disorder	0		1	(0.1)	1	(0.0)
Congenital, Familial And Genetic Disorders	73	(3.4)	91	(4.2)	164	(3.8)
Type V Hyperlipidaemia	21	(1.0)	34	(1.6)	55	(1.3)
Type Iib Hyperlipidaemia	7	(0.3)	4	(0.2)	11	(0.2)
Type Iia Hyperlipidaemia	4	(0.2)	5	(0.2)	9	(0.2)
Thalassaemia	3	(0.1)	2	(0.1)	5	(0.1)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dolichocolon	2	(0.1)	2	(0.1)	4	(0.1)
Factor V Deficiency	1	(0.1)	3	(0.1)	4	(0.1)
Gilbert's Syndrome	1	(0.1)	3	(0.1)	4	(0.1)
Congenital Cystic Kidney Disease	0		3	(0.1)	3	(0.1)
Corneal Dystrophy	2	(0.1)	1	(0.1)	3	(0.1)
Phimosis	3	(0.1)	0		3	(0.1)
Retinitis Pigmentosa	1	(0.1)	2	(0.1)	3	(0.1)
Cerebral Palsy	1	(0.1)	1	(0.1)	2	(0.1)
Deafness Congenital	1	(0.1)	1	(0.1)	2	(0.1)
Factor Ii Mutation	1	(0.1)	1	(0.1)	2	(0.1)
Hereditary Haemochromatosis	0		2	(0.1)	2	(0.1)
Hydrocele	1	(0.1)	1	(0.1)	2	(0.1)
Hypertrophic Cardiomyopathy	0		2	(0.1)	2	(0.1)
Kidney Duplex	2	(0.1)	0		2	(0.1)
Myocardial Bridging	1	(0.1)	1	(0.1)	2	(0.1)
Porokeratosis	0		2	(0.1)	2	(0.1)
Protein S Deficiency	1	(0.1)	1	(0.1)	2	(0.1)
Renal Fusion Anomaly	1	(0.1)	1	(0.1)	2	(0.1)
Alpha-1 Antitrypsin Deficiency	0		1	(0.1)	1	(0.0)
Anophthalmos	1	(0.1)	0		1	(0.0)
Bicuspid Aortic Valve	0		1	(0.1)	1	(0.0)
Blindness Congenital	1	(0.1)	0		1	(0.0)
Block Vertebra	0		1	(0.1)	1	(0.0)
Carney Complex	1	(0.1)	0		1	(0.0)
Colour Blindness	0		1	(0.1)	1	(0.0)
Congenital Astigmatism	0		1	(0.1)	1	(0.0)
Congenital Claw Toe	1	(0.1)	0		1	(0.0)
Congenital Coronary Artery Malformation	0		1	(0.1)	1	(0.0)
Congenital Heart Valve Disorder	0		1	(0.1)	1	(0.0)
Congenital Myopia	0		1	(0.1)	1	(0.0)
Congenital Renal Disorder	0		1	(0.1)	1	(0.0)
Congenital Spinal Stenosis	1	(0.1)	0		1	(0.0)
Congenital Vitreous Anomaly	0		1	(0.1)	1	(0.0)
Connective Tissue Dysplasia	0		1	(0.1)	1	(0.0)
Developmental Hip Dysplasia	0		1	(0.1)	1	(0.0)
Duane's Syndrome	0		1	(0.1)	1	(0.0)
Ectopic Kidney	1	(0.1)	0		1	(0.0)
Factor V Leiden Mutation	0		1	(0.1)	1	(0.0)
Factor Xii Deficiency	1	(0.1)	0		1	(0.0)
Familial Mediterranean Fever	1	(0.1)	0		1	(0.0)
Glucose-6-Phosphate Dehydrogenase Deficiency	1	(0.1)	0		1	(0.0)
Heart Disease Congenital	0		1	(0.1)	1	(0.0)
Hereditary Ataxia	1	(0.1)	0		1	(0.0)
Hereditary Haemorrhagic Telangiectasia	1	(0.1)	0		1	(0.0)
Hereditary Multiple Osteochondromas	1	(0.1)	0		1	(0.0)
Ichthyosis	1	(0.1)	0		1	(0.0)
Iris Coloboma	0		1	(0.1)	1	(0.0)
Kidney Malformation	1	(0.1)	0		1	(0.0)
Klinefelter's Syndrome	1	(0.1)	0		1	(0.0)
Leukodystrophy	1	(0.1)	0		1	(0.0)
Limb Reduction Defect	0		1	(0.1)	1	(0.0)
Pectus Excavatum	0		1	(0.1)	1	(0.0)
Sickle Cell Trait	0		1	(0.1)	1	(0.0)
Spine Malformation	0		1	(0.1)	1	(0.0)
Talipes	0		1	(0.1)	1	(0.0)
Thalassaemia Beta	1	(0.1)	0		1	(0.0)
Thalassaemia Minor	1	(0.1)	0		1	(0.0)
Thyroglossal Cyst	1	(0.1)	0		1	(0.0)
Uvula Aplasia	0		1	(0.1)	1	(0.0)
Wagner's Disease	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant illness at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Injury, Poisoning And Procedural Complications	64	(3.0)	68	(3.1)	132	(3.0)
Meniscus Injury	8	(0.4)	11	(0.5)	19	(0.4)
Post Procedural Hypothyroidism	8	(0.4)	6	(0.3)	14	(0.3)
Muscle Strain	5	(0.2)	3	(0.1)	8	(0.2)
Epicondylitis	3	(0.1)	4	(0.2)	7	(0.2)
Ligament Sprain	3	(0.1)	3	(0.1)	6	(0.1)
Limb Injury	3	(0.1)	3	(0.1)	6	(0.1)
Scar	2	(0.1)	4	(0.2)	6	(0.1)
Contusion	3	(0.1)	2	(0.1)	5	(0.1)
Foot Fracture	3	(0.1)	1	(0.1)	4	(0.1)
Wound	0		4	(0.2)	4	(0.1)
Joint Dislocation	1	(0.1)	2	(0.1)	3	(0.1)
Post Concussion Syndrome	2	(0.1)	1	(0.1)	3	(0.1)
Tendon Rupture	2	(0.1)	1	(0.1)	3	(0.1)
Fall	1	(0.1)	1	(0.1)	2	(0.1)
Head Injury	1	(0.1)	1	(0.1)	2	(0.1)
Joint Injury	1	(0.1)	1	(0.1)	2	(0.1)
Ligament Rupture	0		2	(0.1)	2	(0.1)
Post-Traumatic Neck Syndrome	2	(0.1)	0		2	(0.1)
Procedural Pain	2	(0.1)	0		2	(0.1)
Radius Fracture	0		2	(0.1)	2	(0.1)
Rib Fracture	0		2	(0.1)	2	(0.1)
Spinal Compression Fracture	2	(0.1)	0		2	(0.1)
Spinal Fracture	1	(0.1)	1	(0.1)	2	(0.1)
Tendon Injury	2	(0.1)	0		2	(0.1)
Ankle Fracture	1	(0.1)	0		1	(0.0)
Burns Second Degree	1	(0.1)	0		1	(0.0)
Cervical Vertebral Fracture	0		1	(0.1)	1	(0.0)
Craniocerebral Injury	0		1	(0.1)	1	(0.0)
Deafness Traumatic	1	(0.1)	0		1	(0.0)
Dental Restoration Failure	0		1	(0.1)	1	(0.0)
Exposure To Chemical Pollution	0		1	(0.1)	1	(0.0)
Exposure To Communicable Disease	0		1	(0.1)	1	(0.0)
Exposure To Toxic Agent	0		1	(0.1)	1	(0.0)
Eye Contusion	1	(0.1)	0		1	(0.0)
Eye Injury	0		1	(0.1)	1	(0.0)
Eye Laser Scar	0		1	(0.1)	1	(0.0)
Femur Fracture	1	(0.1)	0		1	(0.0)
Hand Fracture	1	(0.1)	0		1	(0.0)
Incisional Hernia	0		1	(0.1)	1	(0.0)
Incomplete Spinal Fusion	1	(0.1)	0		1	(0.0)
Injury Corneal	0		1	(0.1)	1	(0.0)
Ligament Injury	1	(0.1)	0		1	(0.0)
Lumbar Vertebral Fracture	0		1	(0.1)	1	(0.0)
Median Nerve Injury	0		1	(0.1)	1	(0.0)
Muscle Rupture	0		1	(0.1)	1	(0.0)
Nerve Injury	0		1	(0.1)	1	(0.0)
Post Procedural Complication	1	(0.1)	0		1	(0.0)
Post-Traumatic Pain	1	(0.1)	0		1	(0.0)
Radiation Proctitis	1	(0.1)	0		1	(0.0)
Skeletal Injury	0		1	(0.1)	1	(0.0)
Stab Wound	0		1	(0.1)	1	(0.0)
Thermal Burn	0		1	(0.1)	1	(0.0)
Traumatic Haematoma	1	(0.1)	0		1	(0.0)
Vascular Graft Thrombosis	0		1	(0.1)	1	(0.0)
Wrist Fracture	1	(0.1)	0		1	(0.0)
Uncoded	5	(0.2)	4	(0.2)	9	(0.2)
Uncoded	5	(0.2)	4	(0.2)	9	(0.2)
Product Issues	0		1	(0.1)	1	(0.0)
Embedded Device	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.1.23 Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	1880		1878		3758	
All illnesses	1826	(97.1)	1822	(97.0)	3648	(97.1)
Metabolism And Nutrition Disorders	1475	(78.5)	1484	(79.0)	2959	(78.7)
Dyslipidaemia	648	(34.5)	649	(34.6)	1297	(34.5)
Hyperlipidaemia	496	(26.4)	512	(27.3)	1008	(26.8)
Obesity	376	(20.0)	354	(18.9)	730	(19.4)
Hypercholesterolaemia	201	(10.7)	192	(10.2)	393	(10.5)
Vitamin D Deficiency	129	(6.9)	103	(5.5)	232	(6.2)
Hyperuricaemia	93	(5.0)	97	(5.2)	190	(5.1)
Hypertriglyceridaemia	54	(2.9)	66	(3.5)	120	(3.2)
Gout	41	(2.2)	57	(3.0)	98	(2.6)
Overweight	30	(1.6)	25	(1.3)	55	(1.5)
Vitamin B12 Deficiency	25	(1.3)	18	(1.0)	43	(1.1)
Metabolic Syndrome	11	(0.6)	10	(0.5)	21	(0.6)
Lipid Metabolism Disorder	10	(0.5)	7	(0.4)	17	(0.5)
Iron Deficiency	4	(0.2)	10	(0.5)	14	(0.4)
Central Obesity	7	(0.4)	4	(0.2)	11	(0.3)
Lactose Intolerance	7	(0.4)	3	(0.2)	10	(0.3)
Hyperkalaemia	5	(0.3)	4	(0.2)	9	(0.2)
Hypokalaemia	2	(0.1)	7	(0.4)	9	(0.2)
Hypercalcaemia	5	(0.3)	3	(0.2)	8	(0.2)
Hyponatraemia	4	(0.2)	4	(0.2)	8	(0.2)
Vitamin B Complex Deficiency	6	(0.3)	2	(0.1)	8	(0.2)
Hypomagnesaemia	3	(0.2)	3	(0.2)	6	(0.2)
Abnormal Weight Gain	2	(0.1)	1	(0.1)	3	(0.1)
Diabetic Dyslipidaemia	3	(0.2)	0		3	(0.1)
Folate Deficiency	3	(0.2)	0		3	(0.1)
Hyperglycaemia	1	(0.1)	2	(0.1)	3	(0.1)
Hypochloraemia	1	(0.1)	2	(0.1)	3	(0.1)
Calcium Deficiency	2	(0.1)	0		2	(0.1)
Haemochromatosis	2	(0.1)	0		2	(0.1)
Hyperhomocysteinaemia	1	(0.1)	1	(0.1)	2	(0.1)
Hypocholesterolaemia	0		2	(0.1)	2	(0.1)
Hypovitaminosis	0		2	(0.1)	2	(0.1)
Insulin Resistance	2	(0.1)	0		2	(0.1)
Cholesterosis	0		1	(0.1)	1	(0.0)
Decreased Appetite	1	(0.1)	0		1	(0.0)
Diabetic Ketosis	0		1	(0.1)	1	(0.0)
Glucose Tolerance Impaired	0		1	(0.1)	1	(0.0)
Histamine Intolerance	0		1	(0.1)	1	(0.0)
Hyperinsulinaemia	0		1	(0.1)	1	(0.0)
Hypoalbuminaemia	1	(0.1)	0		1	(0.0)
Hypocalcaemia	1	(0.1)	0		1	(0.0)
Hypoglycaemia	0		1	(0.1)	1	(0.0)
Hypoproteinaemia	0		1	(0.1)	1	(0.0)
Lipoedema	1	(0.1)	0		1	(0.0)
Magnesium Deficiency	0		1	(0.1)	1	(0.0)
Metabolic Disorder	1	(0.1)	0		1	(0.0)
Polydipsia	0		1	(0.1)	1	(0.0)
Tetany	1	(0.1)	0		1	(0.0)
Underweight	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vascular Disorders	1435	(76.3)	1405	(74.8)	2840	(75.6)
Hypertension	1386	(73.7)	1353	(72.0)	2739	(72.9)
Peripheral Arterial Occlusive Disease	87	(4.6)	90	(4.8)	177	(4.7)
Varicose Vein	55	(2.9)	50	(2.7)	105	(2.8)
Peripheral Venous Disease	40	(2.1)	30	(1.6)	70	(1.9)
Aortic Arteriosclerosis	19	(1.0)	31	(1.6)	50	(1.3)
Hypertensive Angiopathy	17	(0.9)	23	(1.2)	40	(1.1)
Arteriosclerosis	16	(0.8)	22	(1.2)	38	(1.0)
Diabetic Vascular Disorder	8	(0.4)	11	(0.6)	19	(0.5)
Peripheral Vascular Disorder	5	(0.3)	8	(0.4)	13	(0.3)
Hot Flush	6	(0.3)	5	(0.3)	11	(0.3)
Peripheral Artery Stenosis	6	(0.3)	5	(0.3)	11	(0.3)
Deep Vein Thrombosis	3	(0.2)	6	(0.3)	9	(0.2)
Essential Hypertension	2	(0.1)	7	(0.4)	9	(0.2)
Aortic Dilatation	3	(0.2)	5	(0.3)	8	(0.2)
Aortic Stenosis	4	(0.2)	3	(0.2)	7	(0.2)
Aortic Aneurysm	4	(0.2)	2	(0.1)	6	(0.2)
Brachiocephalic Arteriosclerosis	2	(0.1)	3	(0.2)	5	(0.1)
Raynaud's Phenomenon	2	(0.1)	3	(0.2)	5	(0.1)
Lymphoedema	3	(0.2)	1	(0.1)	4	(0.1)
Embolism Venous	0		3	(0.2)	3	(0.1)
Thrombophlebitis	1	(0.1)	2	(0.1)	3	(0.1)
Angiopathy	2	(0.1)	0		2	(0.1)
Aortic Dissection	2	(0.1)	0		2	(0.1)
Diabetic Macroangiopathy	2	(0.1)	0		2	(0.1)
Hypotension	1	(0.1)	1	(0.1)	2	(0.1)
Macroangiopathy	2	(0.1)	0		2	(0.1)
Orthostatic Hypotension	2	(0.1)	0		2	(0.1)
Aneurysm	0		1	(0.1)	1	(0.0)
Angiosclerosis	0		1	(0.1)	1	(0.0)
Aortic Disorder	1	(0.1)	0		1	(0.0)
Aortic Thrombosis	1	(0.1)	0		1	(0.0)
Arterial Insufficiency	1	(0.1)	0		1	(0.0)
Arterial Occlusive Disease	1	(0.1)	0		1	(0.0)
Arteriosclerosis Moenckeberg-Type	1	(0.1)	0		1	(0.0)
Atheroembolism	0		1	(0.1)	1	(0.0)
Diabetic Microangiopathy	0		1	(0.1)	1	(0.0)
Giant Cell Arteritis	0		1	(0.1)	1	(0.0)
Granulomatosis With Polyangiitis	0		1	(0.1)	1	(0.0)
Iliac Artery Stenosis	0		1	(0.1)	1	(0.0)
Jugular Vein Distension	0		1	(0.1)	1	(0.0)
Leriche Syndrome	1	(0.1)	0		1	(0.0)
May-Thurner Syndrome	1	(0.1)	0		1	(0.0)
Phlebitis	1	(0.1)	0		1	(0.0)
Spider Vein	1	(0.1)	0		1	(0.0)
Subclavian Artery Stenosis	1	(0.1)	0		1	(0.0)
Subclavian Steal Syndrome	1	(0.1)	0		1	(0.0)
Venous Thrombosis	0		1	(0.1)	1	(0.0)
White Coat Hypertension	1	(0.1)	0		1	(0.0)
Eye Disorders	704	(37.5)	706	(37.6)	1410	(37.5)
Diabetic Retinopathy	311	(16.5)	319	(17.0)	630	(16.8)
Cataract	274	(14.6)	268	(14.3)	542	(14.4)
Glaucoma	79	(4.2)	82	(4.4)	161	(4.3)
Myopia	68	(3.6)	69	(3.7)	137	(3.6)
Presbyopia	59	(3.1)	77	(4.1)	136	(3.6)
Retinopathy Hypertensive	47	(2.5)	45	(2.4)	92	(2.5)
Astigmatism	40	(2.1)	45	(2.4)	85	(2.3)
Hypermetropia	40	(2.1)	44	(2.3)	84	(2.2)
Dry Eye	37	(2.0)	34	(1.8)	71	(1.9)
Diabetic Retinal Oedema	29	(1.5)	33	(1.8)	62	(1.6)
Conjunctivitis Allergic	12	(0.6)	14	(0.8)	26	(0.7)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Macular Degeneration	8	(0.4)	18	(1.0)	26	(0.7)
Refraction Disorder	11	(0.6)	14	(0.8)	25	(0.7)
Arteriosclerotic Retinopathy	12	(0.6)	10	(0.5)	22	(0.6)
Retinal Vascular Disorder	10	(0.5)	12	(0.6)	22	(0.6)
Cataract Nuclear	11	(0.6)	10	(0.5)	21	(0.6)
Ocular Hypertension	11	(0.6)	8	(0.4)	19	(0.5)
Vitreous Detachment	10	(0.5)	9	(0.5)	19	(0.5)
Age-Related Macular Degeneration	8	(0.4)	9	(0.5)	17	(0.5)
Epiretinal Membrane	9	(0.5)	7	(0.4)	16	(0.4)
Visual Acuity Reduced	8	(0.4)	8	(0.4)	16	(0.4)
Amblyopia	7	(0.4)	7	(0.4)	14	(0.4)
Vitreous Degeneration	4	(0.2)	9	(0.5)	13	(0.3)
Chorioretinal Disorder	4	(0.2)	6	(0.3)	10	(0.3)
Vitreous Floaters	7	(0.4)	3	(0.2)	10	(0.3)
Blepharitis	2	(0.1)	7	(0.4)	9	(0.2)
Asthenopia	5	(0.3)	3	(0.2)	8	(0.2)
Eye Disorder	3	(0.2)	5	(0.3)	8	(0.2)
Blindness Unilateral	4	(0.2)	3	(0.2)	7	(0.2)
Retinal Drusen	3	(0.2)	4	(0.2)	7	(0.2)
Vitreous Disorder	5	(0.3)	2	(0.1)	7	(0.2)
Vitreous Opacities	3	(0.2)	4	(0.2)	7	(0.2)
Dry Age-Related Macular Degeneration	2	(0.1)	4	(0.2)	6	(0.2)
Strabismus	1	(0.1)	5	(0.3)	6	(0.2)
Xerophthalmia	5	(0.3)	1	(0.1)	6	(0.2)
Chorioretinal Atrophy	1	(0.1)	4	(0.2)	5	(0.1)
Keratitis	3	(0.2)	2	(0.1)	5	(0.1)
Macular Oedema	3	(0.2)	2	(0.1)	5	(0.1)
Optic Atrophy	4	(0.2)	1	(0.1)	5	(0.1)
Pterygium	3	(0.2)	2	(0.1)	5	(0.1)
Retinal Degeneration	2	(0.1)	3	(0.2)	5	(0.1)
Retinal Detachment	3	(0.2)	2	(0.1)	5	(0.1)
Retinal Disorder	4	(0.2)	1	(0.1)	5	(0.1)
Vision Blurred	3	(0.2)	2	(0.1)	5	(0.1)
Visual Impairment	5	(0.3)	0		5	(0.1)
Corneal Opacity	2	(0.1)	2	(0.1)	4	(0.1)
Dermatochalasis	2	(0.1)	2	(0.1)	4	(0.1)
Hyalosis Asteroid	1	(0.1)	3	(0.2)	4	(0.1)
Maculopathy	3	(0.2)	1	(0.1)	4	(0.1)
Retinal Aneurysm	2	(0.1)	2	(0.1)	4	(0.1)
Retinal Haemorrhage	2	(0.1)	2	(0.1)	4	(0.1)
Conjunctivochalasis	1	(0.1)	2	(0.1)	3	(0.1)
Ectropion	1	(0.1)	2	(0.1)	3	(0.1)
Exfoliation Syndrome	1	(0.1)	2	(0.1)	3	(0.1)
Eyelid Ptosis	2	(0.1)	1	(0.1)	3	(0.1)
Neovascular Age-Related Macular Degeneration	2	(0.1)	1	(0.1)	3	(0.1)
Posterior Capsule Opacification	1	(0.1)	2	(0.1)	3	(0.1)
Retinal Depigmentation	2	(0.1)	1	(0.1)	3	(0.1)
Retinal Dystrophy	1	(0.1)	2	(0.1)	3	(0.1)
Retinal Vein Occlusion	0		3	(0.2)	3	(0.1)
Retinopathy	1	(0.1)	2	(0.1)	3	(0.1)
Aphakia	2	(0.1)	0		2	(0.1)
Blindness	0		2	(0.1)	2	(0.1)
Chalazion	0		2	(0.1)	2	(0.1)
Chorioretinal Scar	1	(0.1)	1	(0.1)	2	(0.1)
Diplopia	0		2	(0.1)	2	(0.1)
Eye Discharge	2	(0.1)	0		2	(0.1)
Eye Haemorrhage	0		2	(0.1)	2	(0.1)
Eyelid Disorder	0		2	(0.1)	2	(0.1)
Iritis	0		2	(0.1)	2	(0.1)
Keratoconus	2	(0.1)	0		2	(0.1)
Macular Scar	1	(0.1)	1	(0.1)	2	(0.1)
Meibomian Gland Dysfunction	0		2	(0.1)	2	(0.1)
Mydriasis	2	(0.1)	0		2	(0.1)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Non-Proliferative Retinopathy	1	(0.1)	1	(0.1)	2	(0.1)
Optic Disc Drusen	1	(0.1)	1	(0.1)	2	(0.1)
Retinal Fibrosis	1	(0.1)	1	(0.1)	2	(0.1)
Retinal Tear	1	(0.1)	1	(0.1)	2	(0.1)
Visual Field Defect	0		2	(0.1)	2	(0.1)
Vitreous Haemorrhage	0		2	(0.1)	2	(0.1)
Amaurosis	1	(0.1)	0		1	(0.0)
Amaurosis Fugax	1	(0.1)	0		1	(0.0)
Angle Closure Glaucoma	0		1	(0.1)	1	(0.0)
Anisometropia	0		1	(0.1)	1	(0.0)
Arcus Lipoides	1	(0.1)	0		1	(0.0)
Cataract Subcapsular	1	(0.1)	0		1	(0.0)
Cholesterolosis Bulbi	0		1	(0.1)	1	(0.0)
Chorioretinopathy	0		1	(0.1)	1	(0.0)
Choroidal Dystrophy	0		1	(0.1)	1	(0.0)
Corneal Defect	1	(0.1)	0		1	(0.0)
Corneal Disorder	0		1	(0.1)	1	(0.0)
Corneal Erosion	0		1	(0.1)	1	(0.0)
Corneal Oedema	1	(0.1)	0		1	(0.0)
Corneal Scar	1	(0.1)	0		1	(0.0)
Detachment Of Retinal Pigment Epithelium	1	(0.1)	0		1	(0.0)
Diabetic Eye Disease	1	(0.1)	0		1	(0.0)
Eczema Eyelids	1	(0.1)	0		1	(0.0)
Endocrine Ophthalmopathy	0		1	(0.1)	1	(0.0)
Episcleritis	0		1	(0.1)	1	(0.0)
Exophthalmos	0		1	(0.1)	1	(0.0)
Eye Pain	0		1	(0.1)	1	(0.0)
Eye Swelling	1	(0.1)	0		1	(0.0)
Eyelid Cyst	1	(0.1)	0		1	(0.0)
Floppy Eyelid Syndrome	0		1	(0.1)	1	(0.0)
Heterophoria	0		1	(0.1)	1	(0.0)
Lacrimal Disorder	0		1	(0.1)	1	(0.0)
Lacrimation Decreased	0		1	(0.1)	1	(0.0)
Lacrimation Increased	1	(0.1)	0		1	(0.0)
Lens Disorder	0		1	(0.1)	1	(0.0)
Lenticular Opacities	0		1	(0.1)	1	(0.0)
Macular Cyst	0		1	(0.1)	1	(0.0)
Macular Hole	1	(0.1)	0		1	(0.0)
Narrow Anterior Chamber Angle	1	(0.1)	0		1	(0.0)
Normal Tension Glaucoma	1	(0.1)	0		1	(0.0)
Ocular Discomfort	0		1	(0.1)	1	(0.0)
Open Angle Glaucoma	1	(0.1)	0		1	(0.0)
Optic Disc Haemorrhage	0		1	(0.1)	1	(0.0)
Optic Nerve Cupping	1	(0.1)	0		1	(0.0)
Pigment Dispersion Syndrome	0		1	(0.1)	1	(0.0)
Pupils Unequal	1	(0.1)	0		1	(0.0)
Retinal Artery Embolism	1	(0.1)	0		1	(0.0)
Retinal Artery Occlusion	0		1	(0.1)	1	(0.0)
Retinal Exudates	1	(0.1)	0		1	(0.0)
Retinal Oedema	1	(0.1)	0		1	(0.0)
Retinal Pigment Epitheliopathy	0		1	(0.1)	1	(0.0)
Retinal Vascular Thrombosis	0		1	(0.1)	1	(0.0)
Retinopathy Proliferative	0		1	(0.1)	1	(0.0)
Scleritis	0		1	(0.1)	1	(0.0)
Subretinal Fibrosis	1	(0.1)	0		1	(0.0)
Swelling Of Eyelid	1	(0.1)	0		1	(0.0)
Symblepharon	1	(0.1)	0		1	(0.0)
Uveitis	0		1	(0.1)	1	(0.0)
Vitreous Loss	0		1	(0.1)	1	(0.0)
Nervous System Disorders	678	(36.1)	683	(36.4)	1361	(36.2)
Diabetic Neuropathy	441	(23.5)	425	(22.6)	866	(23.0)
Headache	35	(1.9)	44	(2.3)	79	(2.1)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Migraine	30	(1.6)	48	(2.6)	78	(2.1)
Carotid Artery Stenosis	30	(1.6)	33	(1.8)	63	(1.7)
Carotid Arteriosclerosis	27	(1.4)	32	(1.7)	59	(1.6)
Carpal Tunnel Syndrome	22	(1.2)	21	(1.1)	43	(1.1)
Sciatica	25	(1.3)	16	(0.8)	41	(1.1)
Myelopathy	23	(1.2)	13	(0.7)	36	(1.0)
Cerebrovascular Accident	12	(0.6)	21	(1.1)	33	(0.9)
Diabetic Autonomic Neuropathy	21	(1.1)	12	(0.6)	33	(0.9)
Restless Legs Syndrome	13	(0.7)	18	(1.0)	31	(0.8)
Cerebrovascular Disorder	10	(0.5)	15	(0.8)	25	(0.7)
Cerebral Arteriosclerosis	5	(0.3)	18	(1.0)	23	(0.6)
Encephalopathy	6	(0.3)	17	(0.9)	23	(0.6)
Neuropathy Peripheral	16	(0.8)	7	(0.4)	23	(0.6)
Dizziness	14	(0.7)	8	(0.4)	22	(0.6)
Carotid Artery Occlusion	4	(0.2)	15	(0.8)	19	(0.5)
Cerebral Ischaemia	5	(0.3)	13	(0.7)	18	(0.5)
Essential Tremor	8	(0.4)	9	(0.5)	17	(0.5)
Cervicobrachial Syndrome	10	(0.5)	4	(0.2)	14	(0.4)
Vascular Encephalopathy	4	(0.2)	10	(0.5)	14	(0.4)
Cervical Radiculopathy	6	(0.3)	7	(0.4)	13	(0.3)
Vertebrobasilar Insufficiency	8	(0.4)	4	(0.2)	12	(0.3)
Amnesia	3	(0.2)	8	(0.4)	11	(0.3)
Paraesthesia	6	(0.3)	5	(0.3)	11	(0.3)
Tension Headache	1	(0.1)	9	(0.5)	10	(0.3)
Hyporeflexia	4	(0.2)	5	(0.3)	9	(0.2)
Lumbar Radiculopathy	5	(0.3)	4	(0.2)	9	(0.2)
Polyneuropathy	2	(0.1)	7	(0.4)	9	(0.2)
Hypoaesthesia	3	(0.2)	5	(0.3)	8	(0.2)
Bell's Palsy	3	(0.2)	4	(0.2)	7	(0.2)
Cauda Equina Syndrome	5	(0.3)	2	(0.1)	7	(0.2)
Epilepsy	3	(0.2)	4	(0.2)	7	(0.2)
Nerve Compression	1	(0.1)	5	(0.3)	6	(0.2)
Neuralgia	3	(0.2)	3	(0.2)	6	(0.2)
Cerebral Infarction	2	(0.1)	3	(0.2)	5	(0.1)
Hypersomnia	2	(0.1)	3	(0.2)	5	(0.1)
Radiculopathy	1	(0.1)	4	(0.2)	5	(0.1)
Cerebrovascular Insufficiency	1	(0.1)	3	(0.2)	4	(0.1)
Diabetic Encephalopathy	0		4	(0.2)	4	(0.1)
Intracranial Aneurysm	2	(0.1)	2	(0.1)	4	(0.1)
Lumbosacral Radiculopathy	1	(0.1)	3	(0.2)	4	(0.1)
Muscle Tone Disorder	2	(0.1)	2	(0.1)	4	(0.1)
Parkinson's Disease	3	(0.2)	1	(0.1)	4	(0.1)
Transient Ischaemic Attack	3	(0.2)	1	(0.1)	4	(0.1)
Tremor	3	(0.2)	1	(0.1)	4	(0.1)
Autonomic Nervous System Imbalance	1	(0.1)	2	(0.1)	3	(0.1)
Brain Stem Ischaemia	1	(0.1)	2	(0.1)	3	(0.1)
Cerebral Atrophy	3	(0.2)	0		3	(0.1)
Hypertonia	0		3	(0.2)	3	(0.1)
Seizure	3	(0.2)	0		3	(0.1)
Sensory Disturbance	1	(0.1)	2	(0.1)	3	(0.1)
Sinus Headache	3	(0.2)	0		3	(0.1)
Balance Disorder	0		2	(0.1)	2	(0.1)
Cerebral Artery Stenosis	0		2	(0.1)	2	(0.1)
Cognitive Disorder	2	(0.1)	0		2	(0.1)
Decreased Vibratory Sense	1	(0.1)	1	(0.1)	2	(0.1)
Guillain-Barre Syndrome	1	(0.1)	1	(0.1)	2	(0.1)
Intercostal Neuralgia	1	(0.1)	1	(0.1)	2	(0.1)
Memory Impairment	1	(0.1)	1	(0.1)	2	(0.1)
Migraine Without Aura	0		2	(0.1)	2	(0.1)
Mononeuropathy	1	(0.1)	1	(0.1)	2	(0.1)
Multiple Sclerosis	1	(0.1)	1	(0.1)	2	(0.1)
Ophthalmic Migraine	1	(0.1)	1	(0.1)	2	(0.1)
Peripheral Sensory Neuropathy	0		2	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Post Herpetic Neuralgia	0		2	(0.1)	2	(0.1)
Somnolence	1	(0.1)	1	(0.1)	2	(0.1)
Trigeminal Neuralgia	1	(0.1)	1	(0.1)	2	(0.1)
Vertebral Artery Stenosis	1	(0.1)	1	(0.1)	2	(0.1)
Anosmia	0		1	(0.1)	1	(0.0)
Arachnoid Cyst	0		1	(0.1)	1	(0.0)
Brain Stem Infarction	1	(0.1)	0		1	(0.0)
Carotid Artery Disease	0		1	(0.1)	1	(0.0)
Carotid Artery Thrombosis	0		1	(0.1)	1	(0.0)
Central Nervous System Lesion	0		1	(0.1)	1	(0.0)
Central Nervous System Vasculitis	1	(0.1)	0		1	(0.0)
Cerebellar Syndrome	0		1	(0.1)	1	(0.0)
Cerebral Calcification	1	(0.1)	0		1	(0.0)
Cerebral Small Vessel Ischaemic Disease	1	(0.1)	0		1	(0.0)
Cerebral Ventricle Dilatation	0		1	(0.1)	1	(0.0)
Chronic Inflammatory Demyelinating Polyradiculoneuropathy	1	(0.1)	0		1	(0.0)
Complex Regional Pain Syndrome	1	(0.1)	0		1	(0.0)
Cubital Tunnel Syndrome	1	(0.1)	0		1	(0.0)
Dementia	1	(0.1)	0		1	(0.0)
Demyelination	1	(0.1)	0		1	(0.0)
Disturbance In Attention	1	(0.1)	0		1	(0.0)
Dizziness Postural	0		1	(0.1)	1	(0.0)
Dyskinesia	1	(0.1)	0		1	(0.0)
Facial Nerve Disorder	0		1	(0.1)	1	(0.0)
Gliosis	1	(0.1)	0		1	(0.0)
Hemiparesis	0		1	(0.1)	1	(0.0)
Hypokinesia	1	(0.1)	0		1	(0.0)
Internal Carotid Artery Deformity	0		1	(0.1)	1	(0.0)
Leukoencephalopathy	1	(0.1)	0		1	(0.0)
Lumbosacral Radiculoplexus Neuropathy	0		1	(0.1)	1	(0.0)
Migraine With Aura	0		1	(0.1)	1	(0.0)
Morton's Neuralgia	1	(0.1)	0		1	(0.0)
Myoclonus	0		1	(0.1)	1	(0.0)
Occipital Neuralgia	0		1	(0.1)	1	(0.0)
Oromandibular Dystonia	1	(0.1)	0		1	(0.0)
Parkinsonism	0		1	(0.1)	1	(0.0)
Peripheral Motor Neuropathy	0		1	(0.1)	1	(0.0)
Peripheral Nerve Lesion	1	(0.1)	0		1	(0.0)
Peripheral Sensorimotor Neuropathy	0		1	(0.1)	1	(0.0)
Peroneal Nerve Palsy	1	(0.1)	0		1	(0.0)
Phantom Limb Syndrome	0		1	(0.1)	1	(0.0)
Pineal Gland Cyst	0		1	(0.1)	1	(0.0)
Piriformis Syndrome	1	(0.1)	0		1	(0.0)
Post Polio Syndrome	0		1	(0.1)	1	(0.0)
Presyncope	0		1	(0.1)	1	(0.0)
Resting Tremor	0		1	(0.1)	1	(0.0)
Syncope	0		1	(0.1)	1	(0.0)
Ulnar Nerve Palsy	0		1	(0.1)	1	(0.0)
Ulnar Tunnel Syndrome	0		1	(0.1)	1	(0.0)
Vascular Headache	1	(0.1)	0		1	(0.0)
Vertebral Artery Occlusion	1	(0.1)	0		1	(0.0)
White Matter Lesion	1	(0.1)	0		1	(0.0)
Musculoskeletal And Connective Tissue Disorders	605	(32.2)	625	(33.3)	1230	(32.7)
Osteoarthritis	195	(10.4)	194	(10.3)	389	(10.3)
Back Pain	115	(6.1)	124	(6.6)	239	(6.4)
Arthralgia	77	(4.1)	76	(4.0)	153	(4.1)
Intervertebral Disc Protrusion	45	(2.4)	54	(2.9)	99	(2.6)
Spinal Osteoarthritis	48	(2.5)	50	(2.7)	98	(2.6)
Arthritis	32	(1.7)	40	(2.1)	72	(1.9)
Osteoporosis	32	(1.7)	37	(2.0)	69	(1.8)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Osteochondrosis	22	(1.2)	34	(1.8)	56	(1.5)
Muscle Spasms	28	(1.5)	26	(1.4)	54	(1.4)
Intervertebral Disc Degeneration	25	(1.3)	20	(1.1)	45	(1.2)
Osteopenia	21	(1.1)	19	(1.0)	40	(1.1)
Intervertebral Disc Disorder	21	(1.1)	17	(0.9)	38	(1.0)
Foot Deformity	13	(0.7)	24	(1.3)	37	(1.0)
Neck Pain	19	(1.0)	16	(0.8)	35	(0.9)
Rotator Cuff Syndrome	12	(0.6)	20	(1.1)	32	(0.8)
Fibromyalgia	15	(0.8)	16	(0.8)	31	(0.8)
Myalgia	9	(0.5)	20	(1.1)	29	(0.8)
Pain In Extremity	16	(0.8)	13	(0.7)	29	(0.8)
Periarthritis	17	(0.9)	12	(0.6)	29	(0.8)
Rheumatoid Arthritis	12	(0.6)	13	(0.7)	25	(0.7)
Back Disorder	11	(0.6)	11	(0.6)	22	(0.6)
Scoliosis	12	(0.6)	10	(0.5)	22	(0.6)
Spinal Pain	9	(0.5)	11	(0.6)	20	(0.5)
Tendonitis	9	(0.5)	11	(0.6)	20	(0.5)
Spinal Stenosis	10	(0.5)	9	(0.5)	19	(0.5)
Bursitis	7	(0.4)	11	(0.6)	18	(0.5)
Exostosis	11	(0.6)	7	(0.4)	18	(0.5)
Plantar Fasciitis	8	(0.4)	6	(0.3)	14	(0.4)
Trigger Finger	5	(0.3)	7	(0.4)	12	(0.3)
Lumbar Spinal Stenosis	6	(0.3)	5	(0.3)	11	(0.3)
Gouty Arthritis	4	(0.2)	6	(0.3)	10	(0.3)
Neuropathic Arthropathy	3	(0.2)	7	(0.4)	10	(0.3)
Psoriatic Arthropathy	7	(0.4)	3	(0.2)	10	(0.3)
Spondylolisthesis	4	(0.2)	6	(0.3)	10	(0.3)
Diastasis Recti Abdominis	3	(0.2)	5	(0.3)	8	(0.2)
Tenosynovitis	2	(0.1)	6	(0.3)	8	(0.2)
Dupuytren's Contracture	5	(0.3)	2	(0.1)	7	(0.2)
Spondylitis	3	(0.2)	4	(0.2)	7	(0.2)
Ankylosing Spondylitis	2	(0.1)	4	(0.2)	6	(0.2)
Joint Range Of Motion Decreased	3	(0.2)	3	(0.2)	6	(0.2)
Synovial Cyst	3	(0.2)	3	(0.2)	6	(0.2)
Arthropathy	0		5	(0.3)	5	(0.1)
Cervical Spinal Stenosis	2	(0.1)	3	(0.2)	5	(0.1)
Musculoskeletal Pain	2	(0.1)	3	(0.2)	5	(0.1)
Musculoskeletal Stiffness	2	(0.1)	3	(0.2)	5	(0.1)
Polyarthritis	3	(0.2)	2	(0.1)	5	(0.1)
Tendon Disorder	4	(0.2)	1	(0.1)	5	(0.1)
Musculoskeletal Chest Pain	2	(0.1)	2	(0.1)	4	(0.1)
Patellofemoral Pain Syndrome	1	(0.1)	3	(0.2)	4	(0.1)
Sacroiliitis	2	(0.1)	2	(0.1)	4	(0.1)
Temporomandibular Joint Syndrome	3	(0.2)	1	(0.1)	4	(0.1)
Tenosynovitis Stenosans	1	(0.1)	3	(0.2)	4	(0.1)
Chondropathy	1	(0.1)	2	(0.1)	3	(0.1)
Enthesopathy	3	(0.2)	0		3	(0.1)
Meniscopathy	2	(0.1)	1	(0.1)	3	(0.1)
Metatarsalgia	2	(0.1)	1	(0.1)	3	(0.1)
Myofascial Pain Syndrome	2	(0.1)	1	(0.1)	3	(0.1)
Nodal Osteoarthritis	3	(0.2)	0		3	(0.1)
Polymyalgia Rheumatica	2	(0.1)	1	(0.1)	3	(0.1)
Sjogren's Syndrome	0		3	(0.2)	3	(0.1)
Systemic Lupus Erythematosus	3	(0.2)	0		3	(0.1)
Bone Formation Increased	1	(0.1)	1	(0.1)	2	(0.1)
Bone Hypertrophy	2	(0.1)	0		2	(0.1)
Chondromalacia	2	(0.1)	0		2	(0.1)
Facet Joint Syndrome	1	(0.1)	1	(0.1)	2	(0.1)
Flank Pain	2	(0.1)	0		2	(0.1)
Knee Deformity	0		2	(0.1)	2	(0.1)
Muscular Weakness	0		2	(0.1)	2	(0.1)
Myofascitis	1	(0.1)	1	(0.1)	2	(0.1)
Myopathy	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Neck Mass	2	(0.1)	0		2	(0.1)
Osteochondritis	1	(0.1)	1	(0.1)	2	(0.1)
Plantar Fascial Fibromatosis	1	(0.1)	1	(0.1)	2	(0.1)
Rheumatic Disorder	2	(0.1)	0		2	(0.1)
Spinal Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Synovitis	2	(0.1)	0		2	(0.1)
Torticollis	0		2	(0.1)	2	(0.1)
Arthritis Reactive	1	(0.1)	0		1	(0.0)
Autoimmune Arthritis	1	(0.1)	0		1	(0.0)
Bone Cyst	0		1	(0.1)	1	(0.0)
Bone Disorder	1	(0.1)	0		1	(0.0)
Bone Loss	0		1	(0.1)	1	(0.0)
Bone Pain	1	(0.1)	0		1	(0.0)
Chondritis	0		1	(0.1)	1	(0.0)
Degenerative Bone Disease	1	(0.1)	0		1	(0.0)
Discoid Meniscus	0		1	(0.1)	1	(0.0)
Fasciitis	1	(0.1)	0		1	(0.0)
Groin Pain	0		1	(0.1)	1	(0.0)
Intervertebral Disc Compression	0		1	(0.1)	1	(0.0)
Intervertebral Disc Space Narrowing	1	(0.1)	0		1	(0.0)
Jaw Cyst	1	(0.1)	0		1	(0.0)
Joint Effusion	0		1	(0.1)	1	(0.0)
Kyphosis	1	(0.1)	0		1	(0.0)
Ligamentitis	0		1	(0.1)	1	(0.0)
Medial Tibial Stress Syndrome	0		1	(0.1)	1	(0.0)
Muscle Tightness	0		1	(0.1)	1	(0.0)
Myosclerosis	1	(0.1)	0		1	(0.0)
Os Trigonum Syndrome	1	(0.1)	0		1	(0.0)
Osteitis Deformans	0		1	(0.1)	1	(0.0)
Osteoarthropathy	1	(0.1)	0		1	(0.0)
Osteonecrosis	0		1	(0.1)	1	(0.0)
Osteoporosis Postmenopausal	0		1	(0.1)	1	(0.0)
Osteosclerosis	1	(0.1)	0		1	(0.0)
Osteosis	0		1	(0.1)	1	(0.0)
Polymyositis	1	(0.1)	0		1	(0.0)
Posterior Tibial Tendon Dysfunction	0		1	(0.1)	1	(0.0)
Psoas Sign	0		1	(0.1)	1	(0.0)
Scleroderma	1	(0.1)	0		1	(0.0)
Seronegative Arthritis	0		1	(0.1)	1	(0.0)
Somatic Dysfunction	0		1	(0.1)	1	(0.0)
Systemic Scleroderma	1	(0.1)	0		1	(0.0)
Tendon Pain	1	(0.1)	0		1	(0.0)
Vertebral Foraminal Stenosis	0		1	(0.1)	1	(0.0)
Vertebral Osteophyte	1	(0.1)	0		1	(0.0)
Gastrointestinal Disorders	526	(28.0)	574	(30.6)	1100	(29.3)
Gastrooesophageal Reflux Disease	229	(12.2)	253	(13.5)	482	(12.8)
Chronic Gastritis	69	(3.7)	79	(4.2)	148	(3.9)
Constipation	73	(3.9)	74	(3.9)	147	(3.9)
Gastritis	32	(1.7)	45	(2.4)	77	(2.0)
Haemorrhoids	38	(2.0)	38	(2.0)	76	(2.0)
Irritable Bowel Syndrome	32	(1.7)	37	(2.0)	69	(1.8)
Hiatus Hernia	27	(1.4)	31	(1.6)	58	(1.5)
Diverticulum	29	(1.5)	24	(1.3)	53	(1.4)
Dyspepsia	21	(1.1)	27	(1.4)	48	(1.3)
Diarrhoea	25	(1.3)	13	(0.7)	38	(1.0)
Large Intestine Polyp	16	(0.8)	21	(1.1)	37	(1.0)
Pancreatitis Chronic	17	(0.9)	19	(1.0)	36	(1.0)
Gastric Polyps	9	(0.5)	13	(0.7)	22	(0.6)
Diverticulum Intestinal	12	(0.6)	9	(0.5)	21	(0.6)
Umbilical Hernia	8	(0.4)	13	(0.7)	21	(0.6)
Colitis	10	(0.5)	8	(0.4)	18	(0.5)
Barrett's Oesophagus	7	(0.4)	9	(0.5)	16	(0.4)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dental Caries	9	(0.5)	5	(0.3)	14	(0.4)
Peptic Ulcer	6	(0.3)	8	(0.4)	14	(0.4)
Dysphagia	5	(0.3)	7	(0.4)	12	(0.3)
Gastric Ulcer	6	(0.3)	6	(0.3)	12	(0.3)
Duodenitis	5	(0.3)	6	(0.3)	11	(0.3)
Inguinal Hernia	3	(0.2)	7	(0.4)	10	(0.3)
Oesophagitis	6	(0.3)	4	(0.2)	10	(0.3)
Pancreatic Steatosis	4	(0.2)	6	(0.3)	10	(0.3)
Abdominal Hernia	4	(0.2)	5	(0.3)	9	(0.2)
Abdominal Pain	5	(0.3)	4	(0.2)	9	(0.2)
Crohn's Disease	5	(0.3)	4	(0.2)	9	(0.2)
Pancreatic Cyst	6	(0.3)	3	(0.2)	9	(0.2)
Duodenal Ulcer	2	(0.1)	6	(0.3)	8	(0.2)
Impaired Gastric Emptying	4	(0.2)	4	(0.2)	8	(0.2)
Periodontal Disease	4	(0.2)	4	(0.2)	8	(0.2)
Abdominal Pain Upper	3	(0.2)	4	(0.2)	7	(0.2)
Nausea	4	(0.2)	3	(0.2)	7	(0.2)
Reflux Gastritis	3	(0.2)	4	(0.2)	7	(0.2)
Abdominal Discomfort	3	(0.2)	3	(0.2)	6	(0.2)
Colitis Ulcerative	2	(0.1)	4	(0.2)	6	(0.2)
Acquired Oesophageal Web	2	(0.1)	3	(0.2)	5	(0.1)
Lumbar Hernia	0		5	(0.3)	5	(0.1)
Pancreatitis	4	(0.2)	1	(0.1)	5	(0.1)
Abdominal Distension	2	(0.1)	2	(0.1)	4	(0.1)
Duodenogastric Reflux	1	(0.1)	3	(0.2)	4	(0.1)
Gastritis Erosive	3	(0.2)	1	(0.1)	4	(0.1)
Gastrointestinal Disorder	1	(0.1)	3	(0.2)	4	(0.1)
Anal Fissure	1	(0.1)	2	(0.1)	3	(0.1)
Erosive Duodenitis	0		3	(0.2)	3	(0.1)
Functional Gastrointestinal Disorder	1	(0.1)	2	(0.1)	3	(0.1)
Gastric Disorder	0		3	(0.2)	3	(0.1)
Rectal Haemorrhage	2	(0.1)	1	(0.1)	3	(0.1)
Vomiting	1	(0.1)	2	(0.1)	3	(0.1)
Acid Peptic Disease	0		2	(0.1)	2	(0.1)
Anal Incontinence	1	(0.1)	1	(0.1)	2	(0.1)
Coeliac Disease	1	(0.1)	1	(0.1)	2	(0.1)
Diaphragmatic Hernia	0		2	(0.1)	2	(0.1)
Duodenal Bulb Deformity	1	(0.1)	1	(0.1)	2	(0.1)
Duodenal Polyp	1	(0.1)	1	(0.1)	2	(0.1)
Enterocolitis	1	(0.1)	1	(0.1)	2	(0.1)
Flatulence	2	(0.1)	0		2	(0.1)
Gastric Xanthoma	1	(0.1)	1	(0.1)	2	(0.1)
Gastrointestinal Wall Thickening	2	(0.1)	0		2	(0.1)
Gastrooesophageal Sphincter Insufficiency	1	(0.1)	1	(0.1)	2	(0.1)
Intestinal Polyp	1	(0.1)	1	(0.1)	2	(0.1)
Oesophageal Polyp	0		2	(0.1)	2	(0.1)
Oesophageal Stenosis	0		2	(0.1)	2	(0.1)
Pancreatic Duct Dilatation	1	(0.1)	1	(0.1)	2	(0.1)
Pancreatic Mass	1	(0.1)	1	(0.1)	2	(0.1)
Poor Dental Condition	0		2	(0.1)	2	(0.1)
Rectal Fissure	0		2	(0.1)	2	(0.1)
Tooth Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Tooth Loss	0		2	(0.1)	2	(0.1)
Abdominal Adhesions	0		1	(0.1)	1	(0.0)
Abdominal Mass	0		1	(0.1)	1	(0.0)
Abdominal Pain Lower	0		1	(0.1)	1	(0.0)
Abdominal Tenderness	1	(0.1)	0		1	(0.0)
Anal Fistula	0		1	(0.1)	1	(0.0)
Anal Polyp	0		1	(0.1)	1	(0.0)
Anal Stenosis	0		1	(0.1)	1	(0.0)
Angular Cheilitis	1	(0.1)	0		1	(0.0)
Anorectal Varices	0		1	(0.1)	1	(0.0)
Ascites	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Colitis Microscopic	1	(0.1)	0		1	(0.0)
Defaecation Urgency	1	(0.1)	0		1	(0.0)
Diabetic Gastroparesis	1	(0.1)	0		1	(0.0)
Diabetic Gastropathy	0		1	(0.1)	1	(0.0)
Dry Mouth	0		1	(0.1)	1	(0.0)
Enterocele	0		1	(0.1)	1	(0.0)
Eosinophilic Oesophagitis	1	(0.1)	0		1	(0.0)
Erosive Oesophagitis	0		1	(0.1)	1	(0.0)
Gastric Mucosa Erythema	1	(0.1)	0		1	(0.0)
Gastrocoele	1	(0.1)	0		1	(0.0)
Gastrointestinal Erosion	1	(0.1)	0		1	(0.0)
Gastrointestinal Polyp	1	(0.1)	0		1	(0.0)
Gastrointestinal Ulcer Haemorrhage	0		1	(0.1)	1	(0.0)
Gastrointestinal Vascular Malformation	0		1	(0.1)	1	(0.0)
Gastrolithiasis	0		1	(0.1)	1	(0.0)
Haemorrhagic Erosive Gastritis	0		1	(0.1)	1	(0.0)
Haemorrhoidal Haemorrhage	1	(0.1)	0		1	(0.0)
Hyperchlorhydria	0		1	(0.1)	1	(0.0)
Ileal Ulcer	1	(0.1)	0		1	(0.0)
Inflammatory Bowel Disease	1	(0.1)	0		1	(0.0)
Intestinal Mass	1	(0.1)	0		1	(0.0)
Intestinal Metaplasia	1	(0.1)	0		1	(0.0)
Large Intestinal Obstruction	1	(0.1)	0		1	(0.0)
Mesenteric Arteriosclerosis	1	(0.1)	0		1	(0.0)
Obstructive Pancreatitis	0		1	(0.1)	1	(0.0)
Oesophageal Achalasia	1	(0.1)	0		1	(0.0)
Pancreatic Enlargement	1	(0.1)	0		1	(0.0)
Pancreatic Failure	1	(0.1)	0		1	(0.0)
Pancreatic Pseudocyst	0		1	(0.1)	1	(0.0)
Pancreatolithiasis	0		1	(0.1)	1	(0.0)
Proctitis	0		1	(0.1)	1	(0.0)
Proctitis Ulcerative	0		1	(0.1)	1	(0.0)
Pseudodiverticular Disease	1	(0.1)	0		1	(0.0)
Rectal Polyp	1	(0.1)	0		1	(0.0)
Rectal Ulcer	1	(0.1)	0		1	(0.0)
Salivary Gland Calculus	1	(0.1)	0		1	(0.0)
Salivary Gland Cyst	0		1	(0.1)	1	(0.0)
Salivary Gland Pain	1	(0.1)	0		1	(0.0)
Stomatitis	1	(0.1)	0		1	(0.0)
Tooth Impacted	1	(0.1)	0		1	(0.0)
Tooth Malformation	1	(0.1)	0		1	(0.0)
Toothache	0		1	(0.1)	1	(0.0)
Trichoglossia	1	(0.1)	0		1	(0.0)
Ulcerative Gastritis	1	(0.1)	0		1	(0.0)
Varices Oesophageal	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Renal And Urinary Disorders	436	(23.2)	455	(24.2)	891	(23.7)
Diabetic Nephropathy	207	(11.0)	203	(10.8)	410	(10.9)
Chronic Kidney Disease	93	(5.0)	113	(6.0)	206	(5.5)
Nephrolithiasis	61	(3.2)	62	(3.3)	123	(3.3)
Renal Cyst	53	(2.8)	53	(2.8)	106	(2.8)
Microalbuminuria	20	(1.1)	18	(1.0)	38	(1.0)
Calculus Urinary	20	(1.1)	13	(0.7)	33	(0.9)
Hypertonic Bladder	14	(0.7)	16	(0.8)	30	(0.8)
Nocturia	6	(0.3)	17	(0.9)	23	(0.6)
Urinary Incontinence	13	(0.7)	8	(0.4)	21	(0.6)
Pollakiuria	11	(0.6)	8	(0.4)	19	(0.5)
Haematuria	11	(0.6)	4	(0.2)	15	(0.4)
Proteinuria	7	(0.4)	5	(0.3)	12	(0.3)
Ureterolithiasis	3	(0.2)	8	(0.4)	11	(0.3)
Dysuria	4	(0.2)	6	(0.3)	10	(0.3)
Stress Urinary Incontinence	2	(0.1)	5	(0.3)	7	(0.2)
Renal Failure	2	(0.1)	4	(0.2)	6	(0.2)
Hydronephrosis	3	(0.2)	2	(0.1)	5	(0.1)
Nephrocalcinosis	1	(0.1)	4	(0.2)	5	(0.1)
Nephropathy	0		5	(0.3)	5	(0.1)
Lower Urinary Tract Symptoms	3	(0.2)	1	(0.1)	4	(0.1)
Micturition Urgency	2	(0.1)	2	(0.1)	4	(0.1)
Hypertensive Nephropathy	1	(0.1)	2	(0.1)	3	(0.1)
Neurogenic Bladder	2	(0.1)	1	(0.1)	3	(0.1)
Renal Colic	2	(0.1)	1	(0.1)	3	(0.1)
Renal Impairment	2	(0.1)	1	(0.1)	3	(0.1)
Renal Mass	1	(0.1)	2	(0.1)	3	(0.1)
Urge Incontinence	2	(0.1)	1	(0.1)	3	(0.1)
Cystitis Interstitial	1	(0.1)	1	(0.1)	2	(0.1)
Polyuria	1	(0.1)	1	(0.1)	2	(0.1)
Renal Artery Stenosis	0		2	(0.1)	2	(0.1)
Renal Disorder	2	(0.1)	0		2	(0.1)
Urinary Tract Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Albuminuria	0		1	(0.1)	1	(0.0)
Bladder Disorder	1	(0.1)	0		1	(0.0)
Bladder Dysfunction	1	(0.1)	0		1	(0.0)
Bladder Irritation	0		1	(0.1)	1	(0.0)
Bladder Prolapse	0		1	(0.1)	1	(0.0)
Calculus Bladder	0		1	(0.1)	1	(0.0)
Contracted Bladder	0		1	(0.1)	1	(0.0)
Glomerulonephritis Membranous	1	(0.1)	0		1	(0.0)
Glycosuria	0		1	(0.1)	1	(0.0)
Incontinence	1	(0.1)	0		1	(0.0)
Kidney Fibrosis	0		1	(0.1)	1	(0.0)
Leukocyturia	0		1	(0.1)	1	(0.0)
Micturition Disorder	1	(0.1)	0		1	(0.0)
Nephrectasia	0		1	(0.1)	1	(0.0)
Nephropathy Toxic	0		1	(0.1)	1	(0.0)
Renal Aneurysm	0		1	(0.1)	1	(0.0)
Renal Artery Arteriosclerosis	1	(0.1)	0		1	(0.0)
Renal Tubular Necrosis	0		1	(0.1)	1	(0.0)
Single Functional Kidney	1	(0.1)	0		1	(0.0)
Tubulointerstitial Nephritis	1	(0.1)	0		1	(0.0)
Ureteric Stenosis	1	(0.1)	0		1	(0.0)
Urethral Stenosis	1	(0.1)	0		1	(0.0)
Urinary Retention	0		1	(0.1)	1	(0.0)
Urinary Tract Obstruction	0		1	(0.1)	1	(0.0)
Urine Flow Decreased	1	(0.1)	0		1	(0.0)
Vesicoureteric Reflux	0		1	(0.1)	1	(0.0)
Cardiac Disorders	437	(23.2)	390	(20.8)	827	(22.0)
Coronary Artery Disease	205	(10.9)	170	(9.1)	375	(10.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Cardiac Failure	88	(4.7)	83	(4.4)	171	(4.5)
Atrial Fibrillation	61	(3.2)	39	(2.1)	100	(2.7)
Bundle Branch Block Right	32	(1.7)	22	(1.2)	54	(1.4)
Coronary Artery Stenosis	16	(0.8)	25	(1.3)	41	(1.1)
Bundle Branch Block Left	18	(1.0)	16	(0.8)	34	(0.9)
Myocardial Infarction	22	(1.2)	11	(0.6)	33	(0.9)
Angina Pectoris	14	(0.7)	18	(1.0)	32	(0.8)
Left Ventricular Hypertrophy	20	(1.1)	8	(0.4)	28	(0.8)
Mitral Valve Incompetence	17	(0.9)	11	(0.6)	28	(0.8)
Ventricular Extrasystoles	12	(0.6)	14	(0.8)	26	(0.7)
Arteriosclerosis Coronary Artery	8	(0.4)	13	(0.7)	21	(0.6)
Tricuspid Valve Incompetence	14	(0.7)	7	(0.4)	21	(0.6)
Sinus Bradycardia	8	(0.4)	12	(0.6)	20	(0.5)
Atrioventricular Block First Degree	10	(0.5)	9	(0.5)	19	(0.5)
Tachycardia	11	(0.6)	8	(0.4)	19	(0.5)
Supraventricular Extrasystoles	9	(0.5)	8	(0.4)	17	(0.5)
Arrhythmia	9	(0.5)	7	(0.4)	16	(0.4)
Hypertensive Heart Disease	8	(0.4)	8	(0.4)	16	(0.4)
Palpitations	7	(0.4)	9	(0.5)	16	(0.4)
Myocardial Ischaemia	9	(0.5)	6	(0.3)	15	(0.4)
Sinus Tachycardia	7	(0.4)	8	(0.4)	15	(0.4)
Supraventricular Tachycardia	8	(0.4)	3	(0.2)	11	(0.3)
Bradycardia	4	(0.2)	5	(0.3)	9	(0.2)
Cardiomegaly	3	(0.2)	5	(0.3)	8	(0.2)
Cardiomyopathy	3	(0.2)	5	(0.3)	8	(0.2)
Left Ventricular Dysfunction	4	(0.2)	4	(0.2)	8	(0.2)
Aortic Valve Incompetence	4	(0.2)	3	(0.2)	7	(0.2)
Cardiac Disorder	5	(0.3)	2	(0.1)	7	(0.2)
Sinus Arrhythmia	2	(0.1)	5	(0.3)	7	(0.2)
Angina Unstable	3	(0.2)	3	(0.2)	6	(0.2)
Atrioventricular Block	2	(0.1)	4	(0.2)	6	(0.2)
Ischaemic Cardiomyopathy	3	(0.2)	3	(0.2)	6	(0.2)
Left Atrial Enlargement	3	(0.2)	3	(0.2)	6	(0.2)
Aortic Valve Sclerosis	3	(0.2)	2	(0.1)	5	(0.1)
Aortic Valve Stenosis	1	(0.1)	4	(0.2)	5	(0.1)
Atrial Flutter	4	(0.2)	1	(0.1)	5	(0.1)
Cardiac Failure Congestive	5	(0.3)	0		5	(0.1)
Metabolic Cardiomyopathy	3	(0.2)	2	(0.1)	5	(0.1)
Myocardial Fibrosis	3	(0.2)	2	(0.1)	5	(0.1)
Diastolic Dysfunction	4	(0.2)	0		4	(0.1)
Extrasystoles	2	(0.1)	2	(0.1)	4	(0.1)
Heart Valve Incompetence	2	(0.1)	2	(0.1)	4	(0.1)
Sinus Node Dysfunction	2	(0.1)	2	(0.1)	4	(0.1)
Ventricular Tachycardia	2	(0.1)	2	(0.1)	4	(0.1)
Left Atrial Dilatation	2	(0.1)	1	(0.1)	3	(0.1)
Pulmonary Valve Incompetence	2	(0.1)	1	(0.1)	3	(0.1)
Aortic Valve Calcification	2	(0.1)	0		2	(0.1)
Bundle Branch Block Bilateral	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac Failure Chronic	1	(0.1)	1	(0.1)	2	(0.1)
Cardiac Ventricular Thrombosis	0		2	(0.1)	2	(0.1)
Cardiovascular Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Congestive Cardiomyopathy	0		2	(0.1)	2	(0.1)
Defect Conduction Intraventricular	1	(0.1)	1	(0.1)	2	(0.1)
Dilatation Atrial	2	(0.1)	0		2	(0.1)
Hypertensive Cardiomyopathy	0		2	(0.1)	2	(0.1)
Left Ventricular Failure	0		2	(0.1)	2	(0.1)
Mitral Valve Disease	0		2	(0.1)	2	(0.1)
Mitral Valve Prolapse	0		2	(0.1)	2	(0.1)
Mitral Valve Stenosis	2	(0.1)	0		2	(0.1)
Tachyarrhythmia	2	(0.1)	0		2	(0.1)
Ventricular Arrhythmia	1	(0.1)	1	(0.1)	2	(0.1)
Aortic Valve Disease	0		1	(0.1)	1	(0.0)
Atrial Enlargement	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Atrial Tachycardia	1	(0.1)	0		1	(0.0)
Atrioventricular Block Second Degree	1	(0.1)	0		1	(0.0)
Bifascicular Block	1	(0.1)	0		1	(0.0)
Cardiac Hypertrophy	0		1	(0.1)	1	(0.0)
Cardiac Valve Disease	1	(0.1)	0		1	(0.0)
Chronic Left Ventricular Failure	0		1	(0.1)	1	(0.0)
Conduction Disorder	0		1	(0.1)	1	(0.0)
Coronary Artery Insufficiency	1	(0.1)	0		1	(0.0)
Gastrocardiac Syndrome	0		1	(0.1)	1	(0.0)
Left Ventricular Diastolic Collapse	1	(0.1)	0		1	(0.0)
Left Ventricular Dilatation	1	(0.1)	0		1	(0.0)
Microvascular Coronary Artery Disease	1	(0.1)	0		1	(0.0)
Mitral Valve Sclerosis	0		1	(0.1)	1	(0.0)
Myocardial Necrosis	0		1	(0.1)	1	(0.0)
Nodal Rhythm	0		1	(0.1)	1	(0.0)
Postinfarction Angina	1	(0.1)	0		1	(0.0)
Prinzmetal Angina	0		1	(0.1)	1	(0.0)
Right Atrial Dilatation	1	(0.1)	0		1	(0.0)
Right Atrial Enlargement	1	(0.1)	0		1	(0.0)
Tricuspid Valve Disease	1	(0.1)	0		1	(0.0)
Ventricular Dysfunction	1	(0.1)	0		1	(0.0)
Ventricular Fibrillation	1	(0.1)	0		1	(0.0)
Ventricular Hypokinesia	1	(0.1)	0		1	(0.0)
Hepatobiliary Disorders	369	(19.6)	396	(21.1)	765	(20.4)
Hepatic Steatosis	264	(14.0)	285	(15.2)	549	(14.6)
Cholelithiasis	44	(2.3)	59	(3.1)	103	(2.7)
Gallbladder Polyp	29	(1.5)	27	(1.4)	56	(1.5)
Nonalcoholic Fatty Liver Disease	23	(1.2)	16	(0.8)	39	(1.0)
Cholecystitis Chronic	13	(0.7)	24	(1.3)	37	(1.0)
Hepatomegaly	15	(0.8)	14	(0.8)	29	(0.8)
Liver Disorder	16	(0.8)	12	(0.6)	28	(0.8)
Hepatic Cyst	12	(0.6)	12	(0.6)	24	(0.6)
Non-Alcoholic Steatohepatitis	9	(0.5)	13	(0.7)	22	(0.6)
Hepatic Function Abnormal	7	(0.4)	14	(0.8)	21	(0.6)
Steatohepatitis	6	(0.3)	5	(0.3)	11	(0.3)
Cholecystitis	5	(0.3)	3	(0.2)	8	(0.2)
Hepatic Lesion	3	(0.2)	4	(0.2)	7	(0.2)
Alcoholic Liver Disease	4	(0.2)	2	(0.1)	6	(0.2)
Biliary Dyskinesia	3	(0.2)	3	(0.2)	6	(0.2)
Hepatitis	1	(0.1)	5	(0.3)	6	(0.2)
Hyperplastic Cholecystopathy	1	(0.1)	5	(0.3)	6	(0.2)
Hepatic Cirrhosis	3	(0.2)	2	(0.1)	5	(0.1)
Bile Duct Stone	3	(0.2)	1	(0.1)	4	(0.1)
Chronic Hepatitis	2	(0.1)	2	(0.1)	4	(0.1)
Gallbladder Disorder	3	(0.2)	1	(0.1)	4	(0.1)
Liver Injury	1	(0.1)	3	(0.2)	4	(0.1)
Hepatic Fibrosis	2	(0.1)	1	(0.1)	3	(0.1)
Hepatic Mass	2	(0.1)	1	(0.1)	3	(0.1)
Hyperbilirubinaemia	1	(0.1)	2	(0.1)	3	(0.1)
Autoimmune Hepatitis	1	(0.1)	1	(0.1)	2	(0.1)
Fatty Liver Alcoholic	0		2	(0.1)	2	(0.1)
Portal Hypertension	1	(0.1)	1	(0.1)	2	(0.1)
Sphincter Of Oddi Dysfunction	2	(0.1)	0		2	(0.1)
Biliary Dilatation	0		1	(0.1)	1	(0.0)
Biliary Tract Disorder	1	(0.1)	0		1	(0.0)
Cholestasis	0		1	(0.1)	1	(0.0)
Cirrhosis Alcoholic	0		1	(0.1)	1	(0.0)
Diabetic Hepatopathy	0		1	(0.1)	1	(0.0)
Gallbladder Cholesterolosis	1	(0.1)	0		1	(0.0)
Hepatic Calcification	1	(0.1)	0		1	(0.0)
Post Cholecystectomy Syndrome	1	(0.1)	0		1	(0.0)
Primary Biliary Cholangitis	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Respiratory, Thoracic And Mediastinal Disorders	365	(19.4)	367	(19.5)	732	(19.5)
Sleep Apnoea Syndrome	166	(8.8)	158	(8.4)	324	(8.6)
Asthma	92	(4.9)	102	(5.4)	194	(5.2)
Rhinitis Allergic	70	(3.7)	65	(3.5)	135	(3.6)
Chronic Obstructive Pulmonary Disease	47	(2.5)	46	(2.5)	93	(2.5)
Pulmonary Mass	15	(0.8)	19	(1.0)	34	(0.9)
Bronchitis Chronic	14	(0.7)	13	(0.7)	27	(0.7)
Cough	7	(0.4)	10	(0.5)	17	(0.5)
Dyspnoea	6	(0.3)	9	(0.5)	15	(0.4)
Emphysema	8	(0.4)	5	(0.3)	13	(0.3)
Nasal Septum Deviation	4	(0.2)	5	(0.3)	9	(0.2)
Dyspnoea Exertional	2	(0.1)	3	(0.2)	5	(0.1)
Nasal Congestion	0		5	(0.3)	5	(0.1)
Pulmonary Fibrosis	2	(0.1)	3	(0.2)	5	(0.1)
Asthma Exercise Induced	1	(0.1)	3	(0.2)	4	(0.1)
Bronchiectasis	2	(0.1)	2	(0.1)	4	(0.1)
Lung Opacity	1	(0.1)	3	(0.2)	4	(0.1)
Pulmonary Hypertension	4	(0.2)	0		4	(0.1)
Vasomotor Rhinitis	2	(0.1)	2	(0.1)	4	(0.1)
Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome	2	(0.1)	1	(0.1)	3	(0.1)
Bronchial Hyperreactivity	1	(0.1)	2	(0.1)	3	(0.1)
Cystic Lung Disease	1	(0.1)	2	(0.1)	3	(0.1)
Allergic Bronchitis	2	(0.1)	0		2	(0.1)
Atelectasis	0		2	(0.1)	2	(0.1)
Cough Variant Asthma	0		2	(0.1)	2	(0.1)
Dysphonia	1	(0.1)	1	(0.1)	2	(0.1)
Epistaxis	1	(0.1)	1	(0.1)	2	(0.1)
Hypoxia	0		2	(0.1)	2	(0.1)
Nasal Dryness	1	(0.1)	1	(0.1)	2	(0.1)
Pleural Effusion	1	(0.1)	1	(0.1)	2	(0.1)
Pulmonary Granuloma	0		2	(0.1)	2	(0.1)
Rhinorrhoea	1	(0.1)	1	(0.1)	2	(0.1)
Sinus Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Acute Respiratory Failure	1	(0.1)	0		1	(0.0)
Allergic Cough	0		1	(0.1)	1	(0.0)
Allergic Pharyngitis	1	(0.1)	0		1	(0.0)
Apnoea	1	(0.1)	0		1	(0.0)
Bronchial Wall Thickening	1	(0.1)	0		1	(0.0)
Epiglottic Cyst	0		1	(0.1)	1	(0.0)
Laryngeal Disorder	0		1	(0.1)	1	(0.0)
Laryngeal Oedema	1	(0.1)	0		1	(0.0)
Lung Consolidation	1	(0.1)	0		1	(0.0)
Lung Disorder	1	(0.1)	0		1	(0.0)
Mediastinal Disorder	1	(0.1)	0		1	(0.0)
Nasal Obstruction	0		1	(0.1)	1	(0.0)
Obstructive Airways Disorder	0		1	(0.1)	1	(0.0)
Paranasal Cyst	1	(0.1)	0		1	(0.0)
Pharyngeal Polyp	0		1	(0.1)	1	(0.0)
Pleural Fibrosis	1	(0.1)	0		1	(0.0)
Pleural Thickening	0		1	(0.1)	1	(0.0)
Pneumonitis	0		1	(0.1)	1	(0.0)
Productive Cough	1	(0.1)	0		1	(0.0)
Pulmonary Embolism	1	(0.1)	0		1	(0.0)
Reflux Laryngitis	1	(0.1)	0		1	(0.0)
Respiratory Distress	1	(0.1)	0		1	(0.0)
Respiratory Failure	1	(0.1)	0		1	(0.0)
Restrictive Pulmonary Disease	1	(0.1)	0		1	(0.0)
Rhinitis Perennial	1	(0.1)	0		1	(0.0)
Sinus Congestion	0		1	(0.1)	1	(0.0)
Snoring	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): NA; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHBODSYS MHDECOD; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y") & (CONTINFL == "Y" & MHLLT != "Type 1 diabetes mellitus" & MHLLT != "Type 2 diabetes mellitus")

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Tracheal Scarring	1	(0.1)	0		1	(0.0)
Upper-Airway Cough Syndrome	0		1	(0.1)	1	(0.0)
Vocal Cord Cyst	1	(0.1)	0		1	(0.0)
Vocal Cord Thickening	0		1	(0.1)	1	(0.0)
Wheezing	1	(0.1)	0		1	(0.0)
Endocrine Disorders	314	(16.7)	333	(17.7)	647	(17.2)
Hypothyroidism	176	(9.4)	196	(10.4)	372	(9.9)
Goitre	60	(3.2)	73	(3.9)	133	(3.5)
Autoimmune Thyroiditis	21	(1.1)	27	(1.4)	48	(1.3)
Hypogonadism	30	(1.6)	13	(0.7)	43	(1.1)
Thyroid Mass	13	(0.7)	21	(1.1)	34	(0.9)
Hyperthyroidism	16	(0.8)	12	(0.6)	28	(0.8)
Testicular Failure	4	(0.2)	5	(0.3)	9	(0.2)
Androgen Deficiency	2	(0.1)	3	(0.2)	5	(0.1)
Hyperparathyroidism Secondary	3	(0.2)	2	(0.1)	5	(0.1)
Hypogonadism Male	2	(0.1)	3	(0.2)	5	(0.1)
Secondary Hypogonadism	3	(0.2)	2	(0.1)	5	(0.1)
Basedow's Disease	3	(0.2)	1	(0.1)	4	(0.1)
Primary Hypothyroidism	3	(0.2)	0		3	(0.1)
Thyroid Cyst	3	(0.2)	0		3	(0.1)
Adrenal Insufficiency	1	(0.1)	1	(0.1)	2	(0.1)
Adrenal Mass	1	(0.1)	1	(0.1)	2	(0.1)
Empty Sella Syndrome	1	(0.1)	1	(0.1)	2	(0.1)
Hyperandrogenism	0		2	(0.1)	2	(0.1)
Hyperparathyroidism	0		2	(0.1)	2	(0.1)
Hypoparathyroidism	0		2	(0.1)	2	(0.1)
Thyroid Calcification	1	(0.1)	1	(0.1)	2	(0.1)
Thyroiditis	1	(0.1)	1	(0.1)	2	(0.1)
Adrenal Disorder	0		1	(0.1)	1	(0.0)
Adrenocortical Insufficiency Acute	0		1	(0.1)	1	(0.0)
Adrenomegaly	0		1	(0.1)	1	(0.0)
Autoimmune Thyroid Disorder	1	(0.1)	0		1	(0.0)
Hyperprolactinaemia	1	(0.1)	0		1	(0.0)
Hypopituitarism	0		1	(0.1)	1	(0.0)
Oestrogen Deficiency	1	(0.1)	0		1	(0.0)
Polyglandular Disorder	0		1	(0.1)	1	(0.0)
Primary Hypoparathyroidism	1	(0.1)	0		1	(0.0)
Thyroid Atrophy	1	(0.1)	0		1	(0.0)
Thyroid Disorder	0		1	(0.1)	1	(0.0)
Thyroiditis Chronic	0		1	(0.1)	1	(0.0)
Toxic Nodular Goitre	1	(0.1)	0		1	(0.0)
Virilism	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Psychiatric Disorders	334	(17.8)	309	(16.4)	643	(17.1)
Depression	169	(9.0)	145	(7.7)	314	(8.4)
Insomnia	93	(5.0)	86	(4.6)	179	(4.8)
Anxiety	83	(4.4)	86	(4.6)	169	(4.5)
Attention Deficit Hyperactivity Disorder	12	(0.6)	14	(0.8)	26	(0.7)
Anxiety Disorder	9	(0.5)	14	(0.8)	23	(0.6)
Major Depression	10	(0.5)	9	(0.5)	19	(0.5)
Generalised Anxiety Disorder	7	(0.4)	8	(0.4)	15	(0.4)
Bipolar Disorder	6	(0.3)	5	(0.3)	11	(0.3)
Nicotine Dependence	5	(0.3)	5	(0.3)	10	(0.3)
Post-Traumatic Stress Disorder	3	(0.2)	7	(0.4)	10	(0.3)
Tobacco Abuse	7	(0.4)	2	(0.1)	9	(0.2)
Sleep Disorder	5	(0.3)	3	(0.2)	8	(0.2)
Panic Attack	5	(0.3)	2	(0.1)	7	(0.2)
Persistent Depressive Disorder	1	(0.1)	5	(0.3)	6	(0.2)
Adjustment Disorder With Depressed Mood	2	(0.1)	3	(0.2)	5	(0.1)
Affective Disorder	3	(0.2)	2	(0.1)	5	(0.1)
Panic Disorder	4	(0.2)	1	(0.1)	5	(0.1)
Depressed Mood	2	(0.1)	1	(0.1)	3	(0.1)
Schizophrenia	1	(0.1)	2	(0.1)	3	(0.1)
Stress	1	(0.1)	2	(0.1)	3	(0.1)
Adjustment Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Bipolar Ii Disorder	2	(0.1)	0		2	(0.1)
Obsessive-Compulsive Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Psychotic Disorder	2	(0.1)	0		2	(0.1)
Acute Stress Disorder	0		1	(0.1)	1	(0.0)
Adjustment Disorder With Anxiety	1	(0.1)	0		1	(0.0)
Alcohol Abuse	1	(0.1)	0		1	(0.0)
Alcoholism	1	(0.1)	0		1	(0.0)
Binge Eating	1	(0.1)	0		1	(0.0)
Cardiovascular Somatic Symptom Disorder	0		1	(0.1)	1	(0.0)
Claustrophobia	1	(0.1)	0		1	(0.0)
Delusional Disorder, Unspecified Type	1	(0.1)	0		1	(0.0)
Drug Dependence	1	(0.1)	0		1	(0.0)
Libido Decreased	1	(0.1)	0		1	(0.0)
Mixed Anxiety And Depressive Disorder	0		1	(0.1)	1	(0.0)
Mood Altered	1	(0.1)	0		1	(0.0)
Neurosis	1	(0.1)	0		1	(0.0)
Parasomnia	1	(0.1)	0		1	(0.0)
Premature Ejaculation	0		1	(0.1)	1	(0.0)
Psychophysiologic Insomnia	0		1	(0.1)	1	(0.0)
Rapid Eye Movement Sleep Behaviour Disorder	0		1	(0.1)	1	(0.0)
Schizoaffective Disorder Depressive Type	0		1	(0.1)	1	(0.0)
Schizophreniform Disorder	1	(0.1)	0		1	(0.0)
Somatic Symptom Disorder	0		1	(0.1)	1	(0.0)
Tic	1	(0.1)	0		1	(0.0)
Reproductive System And Breast Disorders	276	(14.7)	265	(14.1)	541	(14.4)
Benign Prostatic Hyperplasia	118	(6.3)	108	(5.8)	226	(6.0)
Erectile Dysfunction	93	(5.0)	80	(4.3)	173	(4.6)
Prostatomegaly	7	(0.4)	16	(0.8)	23	(0.6)
Ovarian Cyst	8	(0.4)	11	(0.6)	19	(0.5)
Prostatitis	9	(0.5)	9	(0.5)	18	(0.5)
Menopausal Symptoms	8	(0.4)	7	(0.4)	15	(0.4)
Atrophic Vulvovaginitis	6	(0.3)	8	(0.4)	14	(0.4)
Polycystic Ovaries	7	(0.4)	7	(0.4)	14	(0.4)
Breast Fibrosis	1	(0.1)	5	(0.3)	6	(0.2)
Endometriosis	2	(0.1)	4	(0.2)	6	(0.2)
Breast Disorder	2	(0.1)	3	(0.2)	5	(0.1)
Breast Cyst	3	(0.2)	1	(0.1)	4	(0.1)
Breast Hyperplasia	3	(0.2)	1	(0.1)	4	(0.1)
Cervical Dysplasia	2	(0.1)	2	(0.1)	4	(0.1)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): NA; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHBODSYS MHDECOD; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y") & (CONTINFL == "Y" & MHLLT != "Type 1 diabetes mellitus" & MHLLT != "Type 2 diabetes mellitus")

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dysmenorrhoea	3	(0.2)	1	(0.1)	4	(0.1)
Fibrocystic Breast Disease	2	(0.1)	2	(0.1)	4	(0.1)
Gynaecomastia	2	(0.1)	2	(0.1)	4	(0.1)
Uterine Polyp	3	(0.2)	1	(0.1)	4	(0.1)
Uterine Prolapse	3	(0.2)	1	(0.1)	4	(0.1)
Amenorrhoea	1	(0.1)	2	(0.1)	3	(0.1)
Breast Mass	2	(0.1)	1	(0.1)	3	(0.1)
Breast Pain	2	(0.1)	1	(0.1)	3	(0.1)
Cervical Cyst	2	(0.1)	1	(0.1)	3	(0.1)
Infertility	2	(0.1)	1	(0.1)	3	(0.1)
Prostatic Disorder	2	(0.1)	1	(0.1)	3	(0.1)
Vulvovaginal Dryness	2	(0.1)	1	(0.1)	3	(0.1)
Adenomyosis	0		2	(0.1)	2	(0.1)
Calculus Prostatic	1	(0.1)	1	(0.1)	2	(0.1)
Cervix Disorder	1	(0.1)	1	(0.1)	2	(0.1)
Cystocele	1	(0.1)	1	(0.1)	2	(0.1)
Haematospermia	2	(0.1)	0		2	(0.1)
Heavy Menstrual Bleeding	2	(0.1)	0		2	(0.1)
Menstruation Irregular	1	(0.1)	1	(0.1)	2	(0.1)
Organic Erectile Dysfunction	0		2	(0.1)	2	(0.1)
Peyronie's Disease	2	(0.1)	0		2	(0.1)
Prostatic Calcification	1	(0.1)	1	(0.1)	2	(0.1)
Vulvovaginal Discomfort	2	(0.1)	0		2	(0.1)
Artificial Menopause	1	(0.1)	0		1	(0.0)
Balanoposthitis	1	(0.1)	0		1	(0.0)
Breast Calcifications	0		1	(0.1)	1	(0.0)
Breast Discharge	1	(0.1)	0		1	(0.0)
Breast Enlargement	1	(0.1)	0		1	(0.0)
Cervical Polyp	1	(0.1)	0		1	(0.0)
Ectropion Of Cervix	0		1	(0.1)	1	(0.0)
Endometrial Hyperplasia	0		1	(0.1)	1	(0.0)
Endometrial Thickening	0		1	(0.1)	1	(0.0)
Epididymal Cyst	0		1	(0.1)	1	(0.0)
Fallopian Tube Obstruction	1	(0.1)	0		1	(0.0)
Infertility Male	1	(0.1)	0		1	(0.0)
Menopausal Disorder	0		1	(0.1)	1	(0.0)
Menstrual Disorder	1	(0.1)	0		1	(0.0)
Ovarian Mass	0		1	(0.1)	1	(0.0)
Pelvic Adhesions	0		1	(0.1)	1	(0.0)
Pelvic Pain	1	(0.1)	0		1	(0.0)
Premenstrual Syndrome	1	(0.1)	0		1	(0.0)
Prostatic Mass	0		1	(0.1)	1	(0.0)
Prostatism	1	(0.1)	0		1	(0.0)
Pruritus Genital	1	(0.1)	0		1	(0.0)
Rectocele	1	(0.1)	0		1	(0.0)
Scrotal Inflammation	0		1	(0.1)	1	(0.0)
Testicular Atrophy	1	(0.1)	0		1	(0.0)
Testicular Cyst	0		1	(0.1)	1	(0.0)
Testicular Mass	1	(0.1)	0		1	(0.0)
Testicular Swelling	0		1	(0.1)	1	(0.0)
Uterine Disorder	0		1	(0.1)	1	(0.0)
Uterovaginal Prolapse	0		1	(0.1)	1	(0.0)
Vaginal Haemorrhage	1	(0.1)	0		1	(0.0)
Vaginal Prolapse	1	(0.1)	0		1	(0.0)
Varicocele	0		1	(0.1)	1	(0.0)
Vulvovaginal Pruritus	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Immune System Disorders	232	(12.3)	239	(12.7)	471	(12.5)
Seasonal Allergy	120	(6.4)	139	(7.4)	259	(6.9)
Drug Hypersensitivity	73	(3.9)	80	(4.3)	153	(4.1)
Hypersensitivity	29	(1.5)	23	(1.2)	52	(1.4)
Food Allergy	13	(0.7)	13	(0.7)	26	(0.7)
Iodine Allergy	3	(0.2)	6	(0.3)	9	(0.2)
Multiple Allergies	7	(0.4)	2	(0.1)	9	(0.2)
Sarcoidosis	3	(0.2)	6	(0.3)	9	(0.2)
Rubber Sensitivity	5	(0.3)	2	(0.1)	7	(0.2)
Allergy To Arthropod Sting	1	(0.1)	4	(0.2)	5	(0.1)
Allergy To Metals	1	(0.1)	4	(0.2)	5	(0.1)
Anaphylactic Reaction	3	(0.2)	1	(0.1)	4	(0.1)
Dust Allergy	1	(0.1)	3	(0.2)	4	(0.1)
Allergy To Animal	1	(0.1)	2	(0.1)	3	(0.1)
Allergy To Arthropod Bite	1	(0.1)	2	(0.1)	3	(0.1)
Allergy To Vaccine	1	(0.1)	2	(0.1)	3	(0.1)
Contrast Media Allergy	0		3	(0.2)	3	(0.1)
Mite Allergy	0		3	(0.2)	3	(0.1)
Allergy To Chemicals	2	(0.1)	0		2	(0.1)
Allergy To Plants	0		2	(0.1)	2	(0.1)
Immunodeficiency Common Variable	1	(0.1)	0		1	(0.0)
Insulin Autoimmune Syndrome	0		1	(0.1)	1	(0.0)
Loefgren Syndrome	0		1	(0.1)	1	(0.0)
Milk Allergy	0		1	(0.1)	1	(0.0)
Mycotic Allergy	0		1	(0.1)	1	(0.0)
Infections And Infestations	230	(12.2)	193	(10.3)	423	(11.3)
Onychomycosis	25	(1.3)	27	(1.4)	52	(1.4)
Tinea Pedis	30	(1.6)	17	(0.9)	47	(1.2)
Pyelonephritis Chronic	18	(1.0)	23	(1.2)	41	(1.1)
Sinusitis	16	(0.8)	12	(0.6)	28	(0.8)
Dermatophytosis Of Nail	12	(0.6)	15	(0.8)	27	(0.7)
Urinary Tract Infection	14	(0.7)	13	(0.7)	27	(0.7)
Diverticulitis	11	(0.6)	7	(0.4)	18	(0.5)
Rhinitis	9	(0.5)	9	(0.5)	18	(0.5)
Bronchitis	8	(0.4)	7	(0.4)	15	(0.4)
Pharyngitis	7	(0.4)	8	(0.4)	15	(0.4)
Cystitis	6	(0.3)	8	(0.4)	14	(0.4)
Fungal Infection	7	(0.4)	4	(0.2)	11	(0.3)
Conjunctivitis	7	(0.4)	3	(0.2)	10	(0.3)
Vaginal Infection	5	(0.3)	5	(0.3)	10	(0.3)
Chronic Sinusitis	6	(0.3)	3	(0.2)	9	(0.2)
Chronic Tonsillitis	6	(0.3)	1	(0.1)	7	(0.2)
Genital Herpes	5	(0.3)	2	(0.1)	7	(0.2)
Helicobacter Infection	4	(0.2)	3	(0.2)	7	(0.2)
Hiv Infection	3	(0.2)	4	(0.2)	7	(0.2)
Hepatitis B	2	(0.1)	4	(0.2)	6	(0.2)
Herpes Simplex	3	(0.2)	3	(0.2)	6	(0.2)
Oral Herpes	3	(0.2)	3	(0.2)	6	(0.2)
Otitis Media	5	(0.3)	1	(0.1)	6	(0.2)
Chronic Hepatitis B	2	(0.1)	3	(0.2)	5	(0.1)
Vulvovaginal Candidiasis	3	(0.2)	2	(0.1)	5	(0.1)
Body Tinea	2	(0.1)	2	(0.1)	4	(0.1)
Chronic Hepatitis C	3	(0.2)	1	(0.1)	4	(0.1)
Folliculitis	4	(0.2)	0		4	(0.1)
Hepatitis C	3	(0.2)	1	(0.1)	4	(0.1)
Laryngitis	1	(0.1)	3	(0.2)	4	(0.1)
Otitis Media Chronic	2	(0.1)	2	(0.1)	4	(0.1)
Periodontitis	2	(0.1)	2	(0.1)	4	(0.1)
Cellulitis	2	(0.1)	1	(0.1)	3	(0.1)
Fungal Skin Infection	1	(0.1)	2	(0.1)	3	(0.1)
Herpes Virus Infection	1	(0.1)	2	(0.1)	3	(0.1)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): NA; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHBODSYS MHDECOD; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y") & (CONTINFL == "Y" & MHLLT != "Type 1 diabetes mellitus" & MHLLT != "Type 2 diabetes mellitus")

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Labyrinthitis	2	(0.1)	1	(0.1)	3	(0.1)
Otitis Externa	1	(0.1)	2	(0.1)	3	(0.1)
Tinea Versicolour	2	(0.1)	1	(0.1)	3	(0.1)
Vulvovaginal Mycotic Infection	1	(0.1)	2	(0.1)	3	(0.1)
Candida Infection	1	(0.1)	1	(0.1)	2	(0.1)
Covid-19	2	(0.1)	0		2	(0.1)
Furuncle	1	(0.1)	1	(0.1)	2	(0.1)
Gastric Ulcer Helicobacter	1	(0.1)	1	(0.1)	2	(0.1)
Gastroenteritis	1	(0.1)	1	(0.1)	2	(0.1)
Helicobacter Gastritis	2	(0.1)	0		2	(0.1)
Hepatitis Viral	1	(0.1)	1	(0.1)	2	(0.1)
Herpes Zoster	1	(0.1)	1	(0.1)	2	(0.1)
Papilloma Viral Infection	1	(0.1)	1	(0.1)	2	(0.1)
Pyelonephritis	1	(0.1)	1	(0.1)	2	(0.1)
Tinea Cruris	1	(0.1)	1	(0.1)	2	(0.1)
Tooth Abscess	0		2	(0.1)	2	(0.1)
Upper Respiratory Tract Infection	1	(0.1)	1	(0.1)	2	(0.1)
Abdominal Abscess	0		1	(0.1)	1	(0.0)
Acute Sinusitis	0		1	(0.1)	1	(0.0)
Aids Retinopathy	1	(0.1)	0		1	(0.0)
Anal Abscess	1	(0.1)	0		1	(0.0)
Anal Tinea	1	(0.1)	0		1	(0.0)
Arthritis Bacterial	0		1	(0.1)	1	(0.0)
Asymptomatic Bacteriuria	0		1	(0.1)	1	(0.0)
Atypical Pneumonia	1	(0.1)	0		1	(0.0)
Balanitis Candida	0		1	(0.1)	1	(0.0)
Breast Abscess	1	(0.1)	0		1	(0.0)
Chorioretinitis	1	(0.1)	0		1	(0.0)
Dermatitis Infected	0		1	(0.1)	1	(0.0)
Dermatophytosis	1	(0.1)	0		1	(0.0)
Ear Infection	1	(0.1)	0		1	(0.0)
Ear Infection Fungal	1	(0.1)	0		1	(0.0)
Encephalitis	1	(0.1)	0		1	(0.0)
Endocarditis	0		1	(0.1)	1	(0.0)
Epididymitis	0		1	(0.1)	1	(0.0)
Erysipelas	0		1	(0.1)	1	(0.0)
Erythrasma	0		1	(0.1)	1	(0.0)
Genital Herpes Simplex	1	(0.1)	0		1	(0.0)
Genitourinary Tract Infection	1	(0.1)	0		1	(0.0)
Gingivitis	1	(0.1)	0		1	(0.0)
Hepatitis A	0		1	(0.1)	1	(0.0)
Hordeolum	0		1	(0.1)	1	(0.0)
Intervertebral Discitis	1	(0.1)	0		1	(0.0)
Lyme Disease	1	(0.1)	0		1	(0.0)
Mycobacterial Infection	1	(0.1)	0		1	(0.0)
Nasopharyngitis	1	(0.1)	0		1	(0.0)
Oesophageal Candidiasis	1	(0.1)	0		1	(0.0)
Ophthalmic Herpes Zoster	1	(0.1)	0		1	(0.0)
Opisthorchiasis	0		1	(0.1)	1	(0.0)
Peritonitis	0		1	(0.1)	1	(0.0)
Pilonidal Cyst	0		1	(0.1)	1	(0.0)
Pneumonia	1	(0.1)	0		1	(0.0)
Post-Acute Covid-19 Syndrome	1	(0.1)	0		1	(0.0)
Salpingo-Oophoritis	1	(0.1)	0		1	(0.0)
Staphylococcal Infection	1	(0.1)	0		1	(0.0)
Streptococcal Infection	1	(0.1)	0		1	(0.0)
Tinea Infection	1	(0.1)	0		1	(0.0)
Tonsillitis	0		1	(0.1)	1	(0.0)
Tooth Infection	1	(0.1)	0		1	(0.0)
Tornwaldt Bursitis	1	(0.1)	0		1	(0.0)
Tracheitis	1	(0.1)	0		1	(0.0)
Vestibular Neuronitis	0		1	(0.1)	1	(0.0)
Viral Hepatitis Carrier	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Viral Upper Respiratory Tract Infection	0		1	(0.1)	1	(0.0)
Vulvitis	1	(0.1)	0		1	(0.0)
Skin And Subcutaneous Tissue Disorders	193	(10.3)	181	(9.6)	374	(9.9)
Psoriasis	32	(1.7)	29	(1.5)	61	(1.6)
Eczema	22	(1.2)	27	(1.4)	49	(1.3)
Hyperkeratosis	15	(0.8)	13	(0.7)	28	(0.8)
Dermatitis	12	(0.6)	9	(0.5)	21	(0.6)
Rosacea	7	(0.4)	10	(0.5)	17	(0.5)
Actinic Keratosis	12	(0.6)	4	(0.2)	16	(0.4)
Urticaria	8	(0.4)	6	(0.3)	14	(0.4)
Pruritus	8	(0.4)	5	(0.3)	13	(0.3)
Seborrhoeic Dermatitis	10	(0.5)	1	(0.1)	11	(0.3)
Asteatosis	5	(0.3)	5	(0.3)	10	(0.3)
Dermatitis Contact	5	(0.3)	4	(0.2)	9	(0.2)
Diabetic Foot	4	(0.2)	5	(0.3)	9	(0.2)
Ingrowing Nail	5	(0.3)	3	(0.2)	8	(0.2)
Alopecia	5	(0.3)	2	(0.1)	7	(0.2)
Dry Skin	4	(0.2)	3	(0.2)	7	(0.2)
Eczema Asteatotic	1	(0.1)	6	(0.3)	7	(0.2)
Rash	5	(0.3)	2	(0.1)	7	(0.2)
Skin Ulcer	5	(0.3)	2	(0.1)	7	(0.2)
Vitiligo	4	(0.2)	3	(0.2)	7	(0.2)
Acanthosis Nigricans	3	(0.2)	3	(0.2)	6	(0.2)
Acne	1	(0.1)	4	(0.2)	5	(0.1)
Dermatitis Atopic	3	(0.2)	2	(0.1)	5	(0.1)
Solar Lentigo	2	(0.1)	3	(0.2)	5	(0.1)
Androgenetic Alopecia	3	(0.2)	1	(0.1)	4	(0.1)
Dermatitis Allergic	2	(0.1)	2	(0.1)	4	(0.1)
Erythema	2	(0.1)	2	(0.1)	4	(0.1)
Intertrigo	3	(0.2)	1	(0.1)	4	(0.1)
Nail Dystrophy	1	(0.1)	3	(0.2)	4	(0.1)
Skin Lesion	1	(0.1)	3	(0.2)	4	(0.1)
Stasis Dermatitis	1	(0.1)	3	(0.2)	4	(0.1)
Diabetic Dermopathy	1	(0.1)	2	(0.1)	3	(0.1)
Granuloma Annulare	2	(0.1)	1	(0.1)	3	(0.1)
Hand Dermatitis	1	(0.1)	2	(0.1)	3	(0.1)
Hidradenitis	2	(0.1)	1	(0.1)	3	(0.1)
Keloid Scar	1	(0.1)	2	(0.1)	3	(0.1)
Neurodermatitis	1	(0.1)	2	(0.1)	3	(0.1)
Purpura Senile	3	(0.2)	0		3	(0.1)
Xeroderma	2	(0.1)	1	(0.1)	3	(0.1)
Alopecia Areata	2	(0.1)	0		2	(0.1)
Cold Urticaria	1	(0.1)	1	(0.1)	2	(0.1)
Dyshidrotic Eczema	1	(0.1)	1	(0.1)	2	(0.1)
Hirsutism	2	(0.1)	0		2	(0.1)
Hyperhidrosis	0		2	(0.1)	2	(0.1)
Lentigo	0		2	(0.1)	2	(0.1)
Nail Hypertrophy	0		2	(0.1)	2	(0.1)
Necrobiosis Lipoidica Diabeticorum	1	(0.1)	1	(0.1)	2	(0.1)
Night Sweats	2	(0.1)	0		2	(0.1)
Photosensitivity Reaction	1	(0.1)	1	(0.1)	2	(0.1)
Skin Hypertrophy	1	(0.1)	1	(0.1)	2	(0.1)
Telangiectasia	1	(0.1)	1	(0.1)	2	(0.1)
Acquired Digital Fibrokeratoma	1	(0.1)	0		1	(0.0)
Alopecia Totalis	1	(0.1)	0		1	(0.0)
Angioedema	1	(0.1)	0		1	(0.0)
Cutaneous Vasculitis	1	(0.1)	0		1	(0.0)
Decubitus Ulcer	1	(0.1)	0		1	(0.0)
Dermal Cyst	0		1	(0.1)	1	(0.0)
Drug Eruption	0		1	(0.1)	1	(0.0)
Eczema Nummular	0		1	(0.1)	1	(0.0)
Erythema Nodosum	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Hair Disorder	1	(0.1)	0		1	(0.0)
Henoch-Schonlein Purpura	1	(0.1)	0		1	(0.0)
Ingrown Hair	0		1	(0.1)	1	(0.0)
Lichen Planus	1	(0.1)	0		1	(0.0)
Lichen Sclerosus	0		1	(0.1)	1	(0.0)
Lichen Striatus	0		1	(0.1)	1	(0.0)
Mechanical Urticaria	1	(0.1)	0		1	(0.0)
Milia	0		1	(0.1)	1	(0.0)
Miliaria	1	(0.1)	0		1	(0.0)
Nail Atrophy	1	(0.1)	0		1	(0.0)
Nail Bed Inflammation	1	(0.1)	0		1	(0.0)
Nail Discolouration	0		1	(0.1)	1	(0.0)
Nail Disorder	1	(0.1)	0		1	(0.0)
Nail Pigmentation	1	(0.1)	0		1	(0.0)
Nail Pitting	1	(0.1)	0		1	(0.0)
Neuropathic Ulcer	0		1	(0.1)	1	(0.0)
Onychogryphosis	1	(0.1)	0		1	(0.0)
Palmoplantar Pustulosis	1	(0.1)	0		1	(0.0)
Parakeratosis	0		1	(0.1)	1	(0.0)
Parapsoriasis	0		1	(0.1)	1	(0.0)
Pemphigus	0		1	(0.1)	1	(0.0)
Pigmentation Disorder	0		1	(0.1)	1	(0.0)
Precancerous Skin Lesion	0		1	(0.1)	1	(0.0)
Purpura	0		1	(0.1)	1	(0.0)
Rash Papular	0		1	(0.1)	1	(0.0)
Rash Pruritic	0		1	(0.1)	1	(0.0)
Sensitive Skin	1	(0.1)	0		1	(0.0)
Skin Disorder	1	(0.1)	0		1	(0.0)
Skin Fibrosis	1	(0.1)	0		1	(0.0)
Skin Hyperpigmentation	1	(0.1)	0		1	(0.0)
Skin Hypopigmentation	0		1	(0.1)	1	(0.0)
Urticaria Cholinergic	1	(0.1)	0		1	(0.0)
Urticaria Chronic	0		1	(0.1)	1	(0.0)
Xanthelasma	0		1	(0.1)	1	(0.0)
Xanthoma	0		1	(0.1)	1	(0.0)
Social Circumstances	178	(9.5)	159	(8.5)	337	(9.0)
Menopause	98	(5.2)	78	(4.2)	176	(4.7)
Postmenopause	66	(3.5)	68	(3.6)	134	(3.6)
Cardiac Assistance Device User	4	(0.2)	1	(0.1)	5	(0.1)
Hearing Aid User	2	(0.1)	3	(0.2)	5	(0.1)
Tattoo	2	(0.1)	2	(0.1)	4	(0.1)
Tobacco User	3	(0.2)	1	(0.1)	4	(0.1)
Joint Prosthesis User	1	(0.1)	2	(0.1)	3	(0.1)
Corrective Lens User	2	(0.1)	0		2	(0.1)
Andropause	0		1	(0.1)	1	(0.0)
Denture Wearer	0		1	(0.1)	1	(0.0)
Ex-Tobacco User	0		1	(0.1)	1	(0.0)
Eye Prosthesis User	0		1	(0.1)	1	(0.0)
Homosexuality	0		1	(0.1)	1	(0.0)
Limb Prosthesis User	1	(0.1)	0		1	(0.0)
Organ Donor	1	(0.1)	0		1	(0.0)
Physical Abuse	1	(0.1)	0		1	(0.0)
Sexual Abuse	1	(0.1)	0		1	(0.0)
Wheelchair User	1	(0.1)	0		1	(0.0)
Investigations	131	(7.0)	125	(6.7)	256	(6.8)
Blood Cholesterol Increased	17	(0.9)	17	(0.9)	34	(0.9)
Cardiac Murmur	12	(0.6)	15	(0.8)	27	(0.7)
Blood Testosterone Decreased	5	(0.3)	10	(0.5)	15	(0.4)
Hepatic Enzyme Increased	7	(0.4)	8	(0.4)	15	(0.4)
Liver Function Test Increased	11	(0.6)	2	(0.1)	13	(0.3)
Qrs Axis Abnormal	3	(0.2)	9	(0.5)	12	(0.3)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): NA; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHBODSYS MHDECOD; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y") & (CONTINFL == "Y" & MHLLT != "Type 1 diabetes mellitus" & MHLLT != "Type 2 diabetes mellitus")

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Blood Cholesterol	4	(0.2)	6	(0.3)	10	(0.3)
Blood Triglycerides Increased	5	(0.3)	5	(0.3)	10	(0.3)
Transaminases Increased	2	(0.1)	5	(0.3)	7	(0.2)
Prostatic Specific Antigen Increased	4	(0.2)	2	(0.1)	6	(0.2)
Intraocular Pressure Increased	3	(0.2)	2	(0.1)	5	(0.1)
Alanine Aminotransferase Increased	1	(0.1)	3	(0.2)	4	(0.1)
Blood Alkaline Phosphatase Increased	4	(0.2)	0		4	(0.1)
Carotid Bruit	3	(0.2)	1	(0.1)	4	(0.1)
Carotid Intima-Media Thickness Increased	3	(0.2)	1	(0.1)	4	(0.1)
Continuous Glucose Monitoring	1	(0.1)	3	(0.2)	4	(0.1)
Electrocardiogram Abnormal	1	(0.1)	3	(0.2)	4	(0.1)
Electrocardiogram St-T Change	3	(0.2)	1	(0.1)	4	(0.1)
Electrocardiogram T Wave Abnormal	3	(0.2)	1	(0.1)	4	(0.1)
Arthroscopy	1	(0.1)	2	(0.1)	3	(0.1)
Blood Bilirubin Increased	2	(0.1)	1	(0.1)	3	(0.1)
Ejection Fraction	2	(0.1)	1	(0.1)	3	(0.1)
Liver Function Test Abnormal	1	(0.1)	2	(0.1)	3	(0.1)
Vitamin D Decreased	1	(0.1)	2	(0.1)	3	(0.1)
Amylase Increased	2	(0.1)	0		2	(0.1)
Blood Creatine Phosphokinase Increased	2	(0.1)	0		2	(0.1)
Blood Creatinine Increased	0		2	(0.1)	2	(0.1)
Blood Thyroid Stimulating Hormone Increased	0		2	(0.1)	2	(0.1)
Blood Triglycerides Abnormal	1	(0.1)	1	(0.1)	2	(0.1)
Blood Urea Increased	2	(0.1)	0		2	(0.1)
Body Mass Index Increased	2	(0.1)	0		2	(0.1)
Bone Density Decreased	1	(0.1)	1	(0.1)	2	(0.1)
Electrocardiogram Q Waves	1	(0.1)	1	(0.1)	2	(0.1)
Electrocardiogram Qrs Complex Abnormal	2	(0.1)	0		2	(0.1)
Electrocardiogram T Wave Amplitude Decreased	0		2	(0.1)	2	(0.1)
Electrocardiogram T Wave Inversion	1	(0.1)	1	(0.1)	2	(0.1)
Haematocrit Increased	0		2	(0.1)	2	(0.1)
Hepatic Enzyme Abnormal	1	(0.1)	1	(0.1)	2	(0.1)
High Density Lipoprotein Decreased	0		2	(0.1)	2	(0.1)
Monocyte Count Decreased	0		2	(0.1)	2	(0.1)
Platelet Count Decreased	1	(0.1)	1	(0.1)	2	(0.1)
Vitamin B12 Decreased	2	(0.1)	0		2	(0.1)
Weight Increased	1	(0.1)	1	(0.1)	2	(0.1)
Abdominal Bruit	1	(0.1)	0		1	(0.0)
Acid Base Balance Abnormal	0		1	(0.1)	1	(0.0)
Blood Bilirubin Decreased	1	(0.1)	0		1	(0.0)
Blood Creatinine Decreased	0		1	(0.1)	1	(0.0)
Blood Folate Decreased	0		1	(0.1)	1	(0.0)
Blood Potassium Increased	1	(0.1)	0		1	(0.0)
Blood Pressure Decreased	0		1	(0.1)	1	(0.0)
Blood Pressure Increased	0		1	(0.1)	1	(0.0)
Blood Uric Acid Increased	0		1	(0.1)	1	(0.0)
Body Mass Index	0		1	(0.1)	1	(0.0)
Breath Sounds Abnormal	0		1	(0.1)	1	(0.0)
C-Reactive Protein Increased	1	(0.1)	0		1	(0.0)
Colonoscopy	1	(0.1)	0		1	(0.0)
Digestive Enzyme Abnormal	0		1	(0.1)	1	(0.0)
Ejection Fraction Decreased	1	(0.1)	0		1	(0.0)
Electrocardiogram Low Voltage	0		1	(0.1)	1	(0.0)
Electrocardiogram P Wave Abnormal	1	(0.1)	0		1	(0.0)
Electrocardiogram Q Wave Abnormal	1	(0.1)	0		1	(0.0)
Electrocardiogram Qt Prolonged	0		1	(0.1)	1	(0.0)
Electrocardiogram Repolarisation Abnormality	0		1	(0.1)	1	(0.0)
Electrocardiogram St Segment Abnormal	0		1	(0.1)	1	(0.0)
Electrocardiogram St Segment Depression	0		1	(0.1)	1	(0.0)
Electrocardiogram St-T Segment Abnormal	1	(0.1)	0		1	(0.0)
Enzyme Activity Increased	1	(0.1)	0		1	(0.0)
False Positive Investigation Result	1	(0.1)	0		1	(0.0)
Femoral Bruit	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Glomerular Filtration Rate Decreased	0		1	(0.1)	1	(0.0)
Heart Rate Irregular	1	(0.1)	0		1	(0.0)
Hepatitis B Core Antibody Positive	1	(0.1)	0		1	(0.0)
Hepatitis B Surface Antigen Positive	1	(0.1)	0		1	(0.0)
Hepatitis B Virus Test Positive	1	(0.1)	0		1	(0.0)
Hla-B*27 Positive	0		1	(0.1)	1	(0.0)
Hormone Level Abnormal	1	(0.1)	0		1	(0.0)
Lipase Increased	1	(0.1)	0		1	(0.0)
Lipoprotein (A) Increased	0		1	(0.1)	1	(0.0)
Low Density Lipoprotein Increased	1	(0.1)	0		1	(0.0)
Mammogram Abnormal	0		1	(0.1)	1	(0.0)
Monocyte Percentage Decreased	0		1	(0.1)	1	(0.0)
Mononuclear Cell Count Decreased	1	(0.1)	0		1	(0.0)
Mycobacterium Tuberculosis Complex Test Positive	0		1	(0.1)	1	(0.0)
Neutrophil Count Increased	1	(0.1)	0		1	(0.0)
Occult Blood Positive	1	(0.1)	0		1	(0.0)
Oestradiol Increased	0		1	(0.1)	1	(0.0)
Pancreatic Enzymes Increased	1	(0.1)	0		1	(0.0)
Pedal Pulse Abnormal	0		1	(0.1)	1	(0.0)
Progesterone Decreased	1	(0.1)	0		1	(0.0)
Pulse Abnormal	1	(0.1)	0		1	(0.0)
Red Blood Cell Count Decreased	1	(0.1)	0		1	(0.0)
Red Blood Cell Count Increased	1	(0.1)	0		1	(0.0)
Red Blood Cell Sedimentation Rate Increased	1	(0.1)	0		1	(0.0)
Renal Function Test Abnormal	1	(0.1)	0		1	(0.0)
Sensory Level Abnormal	1	(0.1)	0		1	(0.0)
Serum Ferritin Decreased	1	(0.1)	0		1	(0.0)
Sinus Rhythm	1	(0.1)	0		1	(0.0)
Thyroid Function Test Abnormal	1	(0.1)	0		1	(0.0)
Tuberculin Test Positive	1	(0.1)	0		1	(0.0)
Urine Albumin/Creatinine Ratio Increased	1	(0.1)	0		1	(0.0)
Urine Uric Acid Increased	1	(0.1)	0		1	(0.0)
Visual Acuity Tests	0		1	(0.1)	1	(0.0)
Vitamin B12	1	(0.1)	0		1	(0.0)
Vitamin D	0		1	(0.1)	1	(0.0)
Surgical And Medical Procedures	133	(7.1)	113	(6.0)	246	(6.5)
Percutaneous Coronary Intervention	13	(0.7)	17	(0.9)	30	(0.8)
Intraocular Lens Implant	15	(0.8)	13	(0.7)	28	(0.8)
Hysterectomy	11	(0.6)	9	(0.5)	20	(0.5)
Coronary Artery Bypass	12	(0.6)	7	(0.4)	19	(0.5)
Female Sterilisation	10	(0.5)	9	(0.5)	19	(0.5)
Cardiac Pacemaker Insertion	7	(0.4)	2	(0.1)	9	(0.2)
Knee Arthroplasty	4	(0.2)	4	(0.2)	8	(0.2)
Cholecystectomy	6	(0.3)	1	(0.1)	7	(0.2)
Peripheral Revascularisation	3	(0.2)	4	(0.2)	7	(0.2)
Positive Airway Pressure Therapy	4	(0.2)	2	(0.1)	6	(0.2)
Aortic Valve Replacement	2	(0.1)	3	(0.2)	5	(0.1)
Appendicectomy	3	(0.2)	2	(0.1)	5	(0.1)
Leg Amputation	4	(0.2)	1	(0.1)	5	(0.1)
Thyroidectomy	4	(0.2)	1	(0.1)	5	(0.1)
Tonsillectomy	3	(0.2)	2	(0.1)	5	(0.1)
Implantable Defibrillator Insertion	1	(0.1)	3	(0.2)	4	(0.1)
Retinal Laser Coagulation	1	(0.1)	3	(0.2)	4	(0.1)
Cataract Operation	2	(0.1)	1	(0.1)	3	(0.1)
Hip Arthroplasty	2	(0.1)	1	(0.1)	3	(0.1)
Inguinal Hernia Repair	2	(0.1)	1	(0.1)	3	(0.1)
Spinal Fusion Surgery	3	(0.2)	0		3	(0.1)
Vasectomy	2	(0.1)	1	(0.1)	3	(0.1)
Adenoidectomy	0		2	(0.1)	2	(0.1)
Cardiac Resynchronisation Therapy	1	(0.1)	1	(0.1)	2	(0.1)
Carotid Revascularisation	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Coronary Arterial Stent Insertion	1	(0.1)	1	(0.1)	2	(0.1)
Dental Implantation	1	(0.1)	1	(0.1)	2	(0.1)
Gastrectomy	0		2	(0.1)	2	(0.1)
Hernia Repair	0		2	(0.1)	2	(0.1)
Hysterosalpingo-Oophorectomy	2	(0.1)	0		2	(0.1)
Intrauterine Contraception	1	(0.1)	1	(0.1)	2	(0.1)
Knee Operation	1	(0.1)	1	(0.1)	2	(0.1)
Large Intestinal Polypectomy	0		2	(0.1)	2	(0.1)
Lithotripsy	1	(0.1)	1	(0.1)	2	(0.1)
Meniscus Removal	0		2	(0.1)	2	(0.1)
Spinal Nerve Stimulator Implantation	0		2	(0.1)	2	(0.1)
Toe Amputation	0		2	(0.1)	2	(0.1)
Vitrectomy	1	(0.1)	1	(0.1)	2	(0.1)
Anticoagulant Therapy	0		1	(0.1)	1	(0.0)
Arteriovenous Fistula Operation	0		1	(0.1)	1	(0.0)
Brain Stent Insertion	1	(0.1)	0		1	(0.0)
Breast Reconstruction	1	(0.1)	0		1	(0.0)
Cardioversion	0		1	(0.1)	1	(0.0)
Carotid Artery Stent Insertion	0		1	(0.1)	1	(0.0)
Catheter Placement	0		1	(0.1)	1	(0.0)
Choledocholithotomy	1	(0.1)	0		1	(0.0)
Circumcision	0		1	(0.1)	1	(0.0)
Cochlea Implant	1	(0.1)	0		1	(0.0)
Colectomy	1	(0.1)	0		1	(0.0)
Compression Garment Application	0		1	(0.1)	1	(0.0)
Contraception	0		1	(0.1)	1	(0.0)
Eye Prosthesis Insertion	1	(0.1)	0		1	(0.0)
Eye Prosthesis Removal	1	(0.1)	0		1	(0.0)
Finger Amputation	1	(0.1)	0		1	(0.0)
Foot Operation	1	(0.1)	0		1	(0.0)
Gastric Banding	1	(0.1)	0		1	(0.0)
Glaucoma Surgery	0		1	(0.1)	1	(0.0)
Heart Valve Replacement	1	(0.1)	0		1	(0.0)
Hip Surgery	0		1	(0.1)	1	(0.0)
Hysterotomy	1	(0.1)	0		1	(0.0)
Intervertebral Disc Operation	0		1	(0.1)	1	(0.0)
Keratomileusis	1	(0.1)	0		1	(0.0)
Liver Transplant	1	(0.1)	0		1	(0.0)
Mass Excision	0		1	(0.1)	1	(0.0)
Meniscus Operation	1	(0.1)	0		1	(0.0)
Nephrectomy	0		1	(0.1)	1	(0.0)
Oophorectomy Bilateral	1	(0.1)	0		1	(0.0)
Ovarian Cystectomy	1	(0.1)	0		1	(0.0)
Prophylaxis	1	(0.1)	0		1	(0.0)
Rectal Polypectomy	0		1	(0.1)	1	(0.0)
Renal Transplant	1	(0.1)	0		1	(0.0)
Scleral Operation	1	(0.1)	0		1	(0.0)
Thrombosis Prophylaxis	0		1	(0.1)	1	(0.0)
Tooth Restoration	0		1	(0.1)	1	(0.0)
Transurethral Bladder Resection	1	(0.1)	0		1	(0.0)
Transurethral Prostatectomy	0		1	(0.1)	1	(0.0)
Urinary Bladder Suspension	0		1	(0.1)	1	(0.0)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	122	(6.5)	117	(6.2)	239	(6.4)
Uterine Leiomyoma	22	(1.2)	17	(0.9)	39	(1.0)
Benign Neoplasm Of Thyroid Gland	15	(0.8)	13	(0.7)	28	(0.8)
Haemangioma Of Liver	5	(0.3)	12	(0.6)	17	(0.5)
Seborrhoeic Keratosis	7	(0.4)	9	(0.5)	16	(0.4)
Fibroadenoma Of Breast	8	(0.4)	7	(0.4)	15	(0.4)
Lipoma	8	(0.4)	7	(0.4)	15	(0.4)
Melanocytic Naevus	8	(0.4)	4	(0.2)	12	(0.3)
Prostatic Adenoma	5	(0.3)	4	(0.2)	9	(0.2)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): NA; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y")
admh.xpt; variable(s): TRAG1 MHBODSYS MHDECOD; criteria: (POOLGR1 == "T2D pool" & SAFFL == "Y") & (CONTINFL == "Y" & MHLLT != "Type 1 diabetes mellitus" & MHLLT != "Type 2 diabetes mellitus")

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Eye Naevus	2	(0.1)	6	(0.3)	8	(0.2)
Acrochordon	4	(0.2)	2	(0.1)	6	(0.2)
Adrenal Adenoma	2	(0.1)	4	(0.2)	6	(0.2)
Intraductal Papillary Mucinous Neoplasm	3	(0.2)	3	(0.2)	6	(0.2)
Colon Adenoma	2	(0.1)	3	(0.2)	5	(0.1)
Gastrointestinal Tract Adenoma	3	(0.2)	2	(0.1)	5	(0.1)
Basal Cell Carcinoma	3	(0.2)	1	(0.1)	4	(0.1)
Meningioma	0		4	(0.2)	4	(0.1)
Renal Hamartoma	2	(0.1)	2	(0.1)	4	(0.1)
Skin Papilloma	3	(0.2)	1	(0.1)	4	(0.1)
Breast Cancer	1	(0.1)	2	(0.1)	3	(0.1)
Haemangioma Of Bone	1	(0.1)	2	(0.1)	3	(0.1)
Adrenal Neoplasm	1	(0.1)	1	(0.1)	2	(0.1)
Angiomyolipoma	1	(0.1)	1	(0.1)	2	(0.1)
Benign Breast Neoplasm	1	(0.1)	1	(0.1)	2	(0.1)
Benign Lung Neoplasm	0		2	(0.1)	2	(0.1)
Benign Neoplasm Of Choroid	0		2	(0.1)	2	(0.1)
Benign Neoplasm Of Skin	1	(0.1)	1	(0.1)	2	(0.1)
Breast Neoplasm	1	(0.1)	1	(0.1)	2	(0.1)
Haemangioma	1	(0.1)	1	(0.1)	2	(0.1)
Haemangioma Of Skin	2	(0.1)	0		2	(0.1)
Lipoma Of Breast	1	(0.1)	1	(0.1)	2	(0.1)
Neoplasm Skin	1	(0.1)	1	(0.1)	2	(0.1)
Polycythaemia Vera	2	(0.1)	0		2	(0.1)
Adenoma Benign	1	(0.1)	0		1	(0.0)
Angiolipoma	0		1	(0.1)	1	(0.0)
Anogenital Warts	1	(0.1)	0		1	(0.0)
Benign Bone Neoplasm	0		1	(0.1)	1	(0.0)
Benign Lymph Node Neoplasm	1	(0.1)	0		1	(0.0)
Benign Neoplasm	1	(0.1)	0		1	(0.0)
Benign Neoplasm Of Adrenal Gland	1	(0.1)	0		1	(0.0)
Benign Neoplasm Of Cervix Uteri	1	(0.1)	0		1	(0.0)
Benign Neoplasm Of Spinal Cord	1	(0.1)	0		1	(0.0)
Benign Renal Neoplasm	1	(0.1)	0		1	(0.0)
Benign Salivary Gland Neoplasm	0		1	(0.1)	1	(0.0)
Benign Soft Tissue Neoplasm	1	(0.1)	0		1	(0.0)
Bladder Cancer	1	(0.1)	0		1	(0.0)
Blepharal Papilloma	0		1	(0.1)	1	(0.0)
Cholesteatoma	1	(0.1)	0		1	(0.0)
Gallbladder Neoplasm	1	(0.1)	0		1	(0.0)
Gastrointestinal Submucosal Tumour	0		1	(0.1)	1	(0.0)
Intra-Abdominal Haemangioma	1	(0.1)	0		1	(0.0)
Langerhans' Cell Histiocytosis	1	(0.1)	0		1	(0.0)
Leiomyoma	0		1	(0.1)	1	(0.0)
Lymphangioma	0		1	(0.1)	1	(0.0)
Meningeal Neoplasm	0		1	(0.1)	1	(0.0)
Meningioma Benign	0		1	(0.1)	1	(0.0)
Myelodysplastic Syndrome	0		1	(0.1)	1	(0.0)
Myelolipoma	0		1	(0.1)	1	(0.0)
Neuroendocrine Tumour	1	(0.1)	0		1	(0.0)
Neurofibroma	1	(0.1)	0		1	(0.0)
Non-Hodgkin's Lymphoma	1	(0.1)	0		1	(0.0)
Non-Secretory Adenoma Of Pituitary	1	(0.1)	0		1	(0.0)
Pituitary Tumour	0		1	(0.1)	1	(0.0)
Pituitary Tumour Benign	0		1	(0.1)	1	(0.0)
Prostate Cancer	0		1	(0.1)	1	(0.0)
Prostate Cancer Stage I	0		1	(0.1)	1	(0.0)
Skin Cancer	0		1	(0.1)	1	(0.0)
Systemic Mastocytosis	1	(0.1)	0		1	(0.0)
Thyroid Adenoma	1	(0.1)	0		1	(0.0)
Thyroid Neoplasm	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Blood And Lymphatic System Disorders	99	(5.3)	95	(5.1)	194	(5.2)
Anaemia	50	(2.7)	42	(2.2)	92	(2.5)
Iron Deficiency Anaemia	18	(1.0)	22	(1.2)	40	(1.1)
Polycythaemia	8	(0.4)	6	(0.3)	14	(0.4)
Thrombocytopenia	8	(0.4)	3	(0.2)	11	(0.3)
Leukocytosis	3	(0.2)	4	(0.2)	7	(0.2)
Splenomegaly	3	(0.2)	4	(0.2)	7	(0.2)
Anaemia Vitamin B12 Deficiency	1	(0.1)	3	(0.2)	4	(0.1)
Normochromic Anaemia	1	(0.1)	2	(0.1)	3	(0.1)
Thrombocytosis	2	(0.1)	1	(0.1)	3	(0.1)
Lymphadenopathy	2	(0.1)	0		2	(0.1)
Microcytic Anaemia	2	(0.1)	0		2	(0.1)
Microcytosis	2	(0.1)	0		2	(0.1)
Normocytic Anaemia	1	(0.1)	1	(0.1)	2	(0.1)
Anaemia Macrocytic	1	(0.1)	0		1	(0.0)
Antiphospholipid Syndrome	0		1	(0.1)	1	(0.0)
Deficiency Anaemia	1	(0.1)	0		1	(0.0)
Elephantiasis	0		1	(0.1)	1	(0.0)
Eosinophilia	0		1	(0.1)	1	(0.0)
Haemolytic Anaemia	0		1	(0.1)	1	(0.0)
Hypercoagulation	0		1	(0.1)	1	(0.0)
Hyperglobulinaemia	0		1	(0.1)	1	(0.0)
Hypochromic Anaemia	1	(0.1)	0		1	(0.0)
Immune Thrombocytopenia	0		1	(0.1)	1	(0.0)
Increased Tendency To Bruise	1	(0.1)	0		1	(0.0)
Leukopenia	0		1	(0.1)	1	(0.0)
Nephrogenic Anaemia	1	(0.1)	0		1	(0.0)
Normochromic Normocytic Anaemia	1	(0.1)	0		1	(0.0)
Pancytopenia	1	(0.1)	0		1	(0.0)
Paratracheal Lymphadenopathy	0		1	(0.1)	1	(0.0)
Pernicious Anaemia	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
General Disorders And Administration Site Conditions	105	(5.6)	86	(4.6)	191	(5.1)
Fatigue	30	(1.6)	15	(0.8)	45	(1.2)
Drug Intolerance	14	(0.7)	18	(1.0)	32	(0.8)
Oedema Peripheral	12	(0.6)	16	(0.8)	28	(0.8)
Pain	12	(0.6)	9	(0.5)	21	(0.6)
Oedema	8	(0.4)	9	(0.5)	17	(0.5)
Asthenia	7	(0.4)	9	(0.5)	16	(0.4)
Malaise	7	(0.4)	4	(0.2)	11	(0.3)
Chest Pain	7	(0.4)	2	(0.1)	9	(0.2)
Gait Disturbance	4	(0.2)	2	(0.1)	6	(0.2)
Cyst	0		5	(0.3)	5	(0.1)
Hernia	2	(0.1)	2	(0.1)	4	(0.1)
Hypertrophy	3	(0.2)	0		3	(0.1)
Peripheral Swelling	2	(0.1)	1	(0.1)	3	(0.1)
Mass	1	(0.1)	1	(0.1)	2	(0.1)
Nodule	1	(0.1)	1	(0.1)	2	(0.1)
Oedema Due To Renal Disease	2	(0.1)	0		2	(0.1)
Thirst	2	(0.1)	0		2	(0.1)
Calcinosis	1	(0.1)	0		1	(0.0)
Chest Discomfort	1	(0.1)	0		1	(0.0)
Dysplasia	0		1	(0.1)	1	(0.0)
Facial Pain	0		1	(0.1)	1	(0.0)
Fibrosis	0		1	(0.1)	1	(0.0)
Ill-Defined Disorder	0		1	(0.1)	1	(0.0)
Impaired Healing	1	(0.1)	0		1	(0.0)
Lithiasis	0		1	(0.1)	1	(0.0)
Medical Device Pain	0		1	(0.1)	1	(0.0)
Necrosis	1	(0.1)	0		1	(0.0)
Polyp	1	(0.1)	0		1	(0.0)
Pseudocyst	0		1	(0.1)	1	(0.0)
Sense Of Oppression	0		1	(0.1)	1	(0.0)
Temperature Intolerance	1	(0.1)	0		1	(0.0)
Tenderness	1	(0.1)	0		1	(0.0)
Ulcer	1	(0.1)	0		1	(0.0)
Ear And Labyrinth Disorders	78	(4.2)	78	(4.2)	156	(4.2)
Tinnitus	10	(0.5)	13	(0.7)	23	(0.6)
Deafness	10	(0.5)	12	(0.6)	22	(0.6)
Vertigo	15	(0.8)	7	(0.4)	22	(0.6)
Deafness Bilateral	11	(0.6)	7	(0.4)	18	(0.5)
Hypoacusis	9	(0.5)	6	(0.3)	15	(0.4)
Vertigo Positional	7	(0.4)	8	(0.4)	15	(0.4)
Deafness Unilateral	6	(0.3)	5	(0.3)	11	(0.3)
Meniere's Disease	6	(0.3)	5	(0.3)	11	(0.3)
Deafness Neurosensory	2	(0.1)	8	(0.4)	10	(0.3)
Sudden Hearing Loss	2	(0.1)	1	(0.1)	3	(0.1)
Vestibular Ataxia	1	(0.1)	2	(0.1)	3	(0.1)
Eustachian Tube Dysfunction	1	(0.1)	1	(0.1)	2	(0.1)
Tympanic Membrane Perforation	1	(0.1)	1	(0.1)	2	(0.1)
Cerumen Impaction	0		1	(0.1)	1	(0.0)
Ear Pain	0		1	(0.1)	1	(0.0)
Eustachian Tube Disorder	1	(0.1)	0		1	(0.0)
Hyperacusis	0		1	(0.1)	1	(0.0)
Inner Ear Disorder	1	(0.1)	0		1	(0.0)
Motion Sickness	0		1	(0.1)	1	(0.0)
Presbyacusis	0		1	(0.1)	1	(0.0)
Tympanic Membrane Disorder	0		1	(0.1)	1	(0.0)
Vestibular Disorder	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Congenital, Familial And Genetic Disorders	65	(3.5)	79	(4.2)	144	(3.8)
Type V Hyperlipidaemia	21	(1.1)	33	(1.8)	54	(1.4)
Type Iib Hyperlipidaemia	6	(0.3)	4	(0.2)	10	(0.3)
Type Iia Hyperlipidaemia	2	(0.1)	5	(0.3)	7	(0.2)
Thalassaemia	3	(0.2)	2	(0.1)	5	(0.1)
Dolichocolon	2	(0.1)	2	(0.1)	4	(0.1)
Congenital Cystic Kidney Disease	0		3	(0.2)	3	(0.1)
Factor V Deficiency	1	(0.1)	2	(0.1)	3	(0.1)
Phimosis	3	(0.2)	0		3	(0.1)
Retinitis Pigmentosa	1	(0.1)	2	(0.1)	3	(0.1)
Deafness Congenital	1	(0.1)	1	(0.1)	2	(0.1)
Factor Ii Mutation	1	(0.1)	1	(0.1)	2	(0.1)
Gilbert's Syndrome	1	(0.1)	1	(0.1)	2	(0.1)
Hereditary Haemochromatosis	0		2	(0.1)	2	(0.1)
Hydrocele	1	(0.1)	1	(0.1)	2	(0.1)
Hypertrophic Cardiomyopathy	0		2	(0.1)	2	(0.1)
Kidney Duplex	2	(0.1)	0		2	(0.1)
Myocardial Bridging	1	(0.1)	1	(0.1)	2	(0.1)
Protein S Deficiency	1	(0.1)	1	(0.1)	2	(0.1)
Renal Fusion Anomaly	1	(0.1)	1	(0.1)	2	(0.1)
Alpha-1 Antitrypsin Deficiency	0		1	(0.1)	1	(0.0)
Anophthalmos	1	(0.1)	0		1	(0.0)
Blindness Congenital	1	(0.1)	0		1	(0.0)
Cerebral Palsy	0		1	(0.1)	1	(0.0)
Colour Blindness	0		1	(0.1)	1	(0.0)
Congenital Astigmatism	0		1	(0.1)	1	(0.0)
Congenital Claw Toe	1	(0.1)	0		1	(0.0)
Congenital Myopia	0		1	(0.1)	1	(0.0)
Congenital Renal Disorder	0		1	(0.1)	1	(0.0)
Congenital Spinal Stenosis	1	(0.1)	0		1	(0.0)
Congenital Vitreous Anomaly	0		1	(0.1)	1	(0.0)
Corneal Dystrophy	0		1	(0.1)	1	(0.0)
Developmental Hip Dysplasia	0		1	(0.1)	1	(0.0)
Duane's Syndrome	0		1	(0.1)	1	(0.0)
Ectopic Kidney	1	(0.1)	0		1	(0.0)
Factor V Leiden Mutation	0		1	(0.1)	1	(0.0)
Factor Xii Deficiency	1	(0.1)	0		1	(0.0)
Glucose-6-Phosphate Dehydrogenase Deficiency	1	(0.1)	0		1	(0.0)
Hereditary Ataxia	1	(0.1)	0		1	(0.0)
Hereditary Haemorrhagic Telangiectasia	1	(0.1)	0		1	(0.0)
Hereditary Multiple Osteochondromas	1	(0.1)	0		1	(0.0)
Ichthyosis	1	(0.1)	0		1	(0.0)
Iris Coloboma	0		1	(0.1)	1	(0.0)
Kidney Malformation	1	(0.1)	0		1	(0.0)
Klinefelter's Syndrome	1	(0.1)	0		1	(0.0)
Leukodystrophy	1	(0.1)	0		1	(0.0)
Limb Reduction Defect	0		1	(0.1)	1	(0.0)
Porokeratosis	0		1	(0.1)	1	(0.0)
Sickle Cell Trait	0		1	(0.1)	1	(0.0)
Spine Malformation	0		1	(0.1)	1	(0.0)
Talipes	0		1	(0.1)	1	(0.0)
Thalassaemia Beta	1	(0.1)	0		1	(0.0)
Thalassaemia Minor	1	(0.1)	0		1	(0.0)
Thyroglossal Cyst	1	(0.1)	0		1	(0.0)
Uvula Aplasia	0		1	(0.1)	1	(0.0)
Wagner's Disease	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant illness at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Injury, Poisoning And Procedural Complications	59	(3.1)	62	(3.3)	121	(3.2)
Meniscus Injury	7	(0.4)	10	(0.5)	17	(0.5)
Post Procedural Hypothyroidism	8	(0.4)	5	(0.3)	13	(0.3)
Epicondylitis	3	(0.2)	4	(0.2)	7	(0.2)
Muscle Strain	4	(0.2)	3	(0.2)	7	(0.2)
Ligament Sprain	3	(0.2)	3	(0.2)	6	(0.2)
Limb Injury	3	(0.2)	3	(0.2)	6	(0.2)
Contusion	3	(0.2)	2	(0.1)	5	(0.1)
Scar	1	(0.1)	4	(0.2)	5	(0.1)
Foot Fracture	3	(0.2)	1	(0.1)	4	(0.1)
Joint Dislocation	1	(0.1)	2	(0.1)	3	(0.1)
Post Concussion Syndrome	2	(0.1)	1	(0.1)	3	(0.1)
Wound	0		3	(0.2)	3	(0.1)
Fall	1	(0.1)	1	(0.1)	2	(0.1)
Head Injury	1	(0.1)	1	(0.1)	2	(0.1)
Joint Injury	1	(0.1)	1	(0.1)	2	(0.1)
Ligament Rupture	0		2	(0.1)	2	(0.1)
Post-Traumatic Neck Syndrome	2	(0.1)	0		2	(0.1)
Rib Fracture	0		2	(0.1)	2	(0.1)
Spinal Compression Fracture	2	(0.1)	0		2	(0.1)
Spinal Fracture	1	(0.1)	1	(0.1)	2	(0.1)
Tendon Injury	2	(0.1)	0		2	(0.1)
Tendon Rupture	2	(0.1)	0		2	(0.1)
Ankle Fracture	1	(0.1)	0		1	(0.0)
Burns Second Degree	1	(0.1)	0		1	(0.0)
Cervical Vertebral Fracture	0		1	(0.1)	1	(0.0)
Craniocerebral Injury	0		1	(0.1)	1	(0.0)
Deafness Traumatic	1	(0.1)	0		1	(0.0)
Dental Restoration Failure	0		1	(0.1)	1	(0.0)
Exposure To Chemical Pollution	0		1	(0.1)	1	(0.0)
Exposure To Communicable Disease	0		1	(0.1)	1	(0.0)
Exposure To Toxic Agent	0		1	(0.1)	1	(0.0)
Eye Contusion	1	(0.1)	0		1	(0.0)
Eye Injury	0		1	(0.1)	1	(0.0)
Femur Fracture	1	(0.1)	0		1	(0.0)
Hand Fracture	1	(0.1)	0		1	(0.0)
Incisional Hernia	0		1	(0.1)	1	(0.0)
Incomplete Spinal Fusion	1	(0.1)	0		1	(0.0)
Injury Corneal	0		1	(0.1)	1	(0.0)
Ligament Injury	1	(0.1)	0		1	(0.0)
Lumbar Vertebral Fracture	0		1	(0.1)	1	(0.0)
Median Nerve Injury	0		1	(0.1)	1	(0.0)
Muscle Rupture	0		1	(0.1)	1	(0.0)
Nerve Injury	0		1	(0.1)	1	(0.0)
Post Procedural Complication	1	(0.1)	0		1	(0.0)
Procedural Pain	1	(0.1)	0		1	(0.0)
Radiation Proctitis	1	(0.1)	0		1	(0.0)
Radius Fracture	0		1	(0.1)	1	(0.0)
Skeletal Injury	0		1	(0.1)	1	(0.0)
Stab Wound	0		1	(0.1)	1	(0.0)
Thermal Burn	0		1	(0.1)	1	(0.0)
Traumatic Haematoma	1	(0.1)	0		1	(0.0)
Vascular Graft Thrombosis	0		1	(0.1)	1	(0.0)
Wrist Fracture	1	(0.1)	0		1	(0.0)
Uncoded	5	(0.3)	3	(0.2)	8	(0.2)
Uncoded	5	(0.3)	3	(0.2)	8	(0.2)
Product Issues	0		1	(0.1)	1	(0.0)
Embedded Device	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.24 Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	2170		2170		4340	
All medications	2170	(100.0)	2169	(100.0)	4339	(100.0)
Biguanides, A10ba	1627	(75.0)	1601	(73.8)	3228	(74.4)
Metformin	1177	(54.2)	1130	(52.1)	2307	(53.2)
Metformin Hydrochloride	458	(21.1)	478	(22.0)	936	(21.6)
Metformin Embonate	2	(0.1)	1	(0.1)	3	(0.1)
Hmg Coa Reductase Inhibitors, C10aa	1276	(58.8)	1230	(56.7)	2506	(57.7)
Atorvastatin	431	(19.9)	422	(19.4)	853	(19.6)
Rosuvastatin Calcium	193	(8.9)	206	(9.5)	399	(9.2)
Rosuvastatin	199	(9.2)	189	(8.7)	388	(8.9)
Atorvastatin Calcium	182	(8.4)	180	(8.3)	362	(8.3)
Simvastatin	157	(7.2)	130	(6.0)	287	(6.6)
Pravastatin	52	(2.4)	39	(1.8)	91	(2.1)
Pitavastatin Calcium	39	(1.8)	36	(1.7)	75	(1.7)
Pravastatin Sodium	9	(0.4)	16	(0.7)	25	(0.6)
Lovastatin	7	(0.3)	9	(0.4)	16	(0.4)
Pitavastatin	6	(0.3)	4	(0.2)	10	(0.2)
Fluvastatin Sodium	1	(0.1)	3	(0.1)	4	(0.1)
Fluvastatin	3	(0.1)	0		3	(0.1)
Atorvastatin Calcium Trihydrate	0		1	(0.1)	1	(0.0)
Insulins And Analogues For Injection, Long-Acting, A10ae	806	(37.1)	806	(37.1)	1612	(37.1)
Insulin Glargine	484	(22.3)	480	(22.1)	964	(22.2)
Insulin Degludec	269	(12.4)	254	(11.7)	523	(12.1)
Insulin Detemir	41	(1.9)	53	(2.4)	94	(2.2)
Insulin Glargine Biosimilar 1	13	(0.6)	20	(0.9)	33	(0.8)
Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors, A10bk	711	(32.8)	675	(31.1)	1386	(31.9)
Empagliflozin	326	(15.0)	285	(13.1)	611	(14.1)
Dapagliflozin	157	(7.2)	148	(6.8)	305	(7.0)
Dapagliflozin Propanediol Monohydrate	107	(4.9)	118	(5.4)	225	(5.2)
Canagliflozin	83	(3.8)	90	(4.2)	173	(4.0)
Ipragliflozin L-Proline	13	(0.6)	16	(0.7)	29	(0.7)
Tofogliflozin	11	(0.5)	5	(0.2)	16	(0.4)
Ipragliflozin	5	(0.2)	4	(0.2)	9	(0.2)
Ertugliflozin	5	(0.2)	3	(0.1)	8	(0.2)
Luseogliflozin	4	(0.2)	3	(0.1)	7	(0.2)
Ertugliflozin Pidolate	0		5	(0.2)	5	(0.1)
Sulfonylureas, A10bb	645	(29.7)	652	(30.1)	1297	(29.9)
Gliclazide	278	(12.8)	290	(13.4)	568	(13.1)
Glimepiride	227	(10.5)	224	(10.3)	451	(10.4)
Glipizide	79	(3.6)	88	(4.1)	167	(3.9)
Glibenclamide	61	(2.8)	49	(2.3)	110	(2.5)
Gliquidone	2	(0.1)	2	(0.1)	4	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ace Inhibitors, Plain, C09aa	589	(27.1)	583	(26.9)	1172	(27.0)
Lisinopril	181	(8.3)	188	(8.7)	369	(8.5)
Ramipril	148	(6.8)	136	(6.3)	284	(6.5)
Perindopril	101	(4.7)	138	(6.4)	239	(5.5)
Enalapril	68	(3.1)	49	(2.3)	117	(2.7)
Perindopril Erbumine	33	(1.5)	16	(0.7)	49	(1.1)
Benazepril	16	(0.7)	10	(0.5)	26	(0.6)
Enalapril Maleate	5	(0.2)	9	(0.4)	14	(0.3)
Perindopril Arginine	7	(0.3)	6	(0.3)	13	(0.3)
Trandolapril	9	(0.4)	4	(0.2)	13	(0.3)
Fosinopril	3	(0.1)	4	(0.2)	7	(0.2)
Benazepril Hydrochloride	4	(0.2)	2	(0.1)	6	(0.1)
Enalaprilat	0		5	(0.2)	5	(0.1)
Lisinopril Dihydrate	2	(0.1)	3	(0.1)	5	(0.1)
Quinapril	2	(0.1)	3	(0.1)	5	(0.1)
Quinapril Hydrochloride	2	(0.1)	3	(0.1)	5	(0.1)
Captopril	2	(0.1)	2	(0.1)	4	(0.1)
Imidapril Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Zofenopril Calcium	2	(0.1)	1	(0.1)	3	(0.1)
Fosinopril Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Alacepril	1	(0.1)	0		1	(0.0)
Delapril	0		1	(0.1)	1	(0.0)
Imidapril	1	(0.1)	0		1	(0.0)
Temocapril Hydrochloride	1	(0.1)	0		1	(0.0)
Platelet Aggregation Inhibitors Excl. Heparin, B01ac	566	(26.1)	563	(25.9)	1129	(26.0)
Acetylsalicylic Acid	498	(22.9)	479	(22.1)	977	(22.5)
Clopidogrel Bisulfate	46	(2.1)	40	(1.8)	86	(2.0)
Clopidogrel	47	(2.2)	38	(1.8)	85	(2.0)
Cilostazol	9	(0.4)	10	(0.5)	19	(0.4)
Acetylsalicylic Acid; Magnesium Hydroxide	6	(0.3)	12	(0.6)	18	(0.4)
Ticagrelor	5	(0.2)	6	(0.3)	11	(0.2)
Acetylsalicylic Acid; Magnesium	1	(0.1)	6	(0.3)	7	(0.2)
Acetylsalicylate Lysine	5	(0.2)	1	(0.1)	6	(0.1)
Prasugrel	2	(0.1)	2	(0.1)	4	(0.1)
Sarpogrelate Hydrochloride	0		4	(0.2)	4	(0.1)
Acetylsalicylic Acid; Clopidogrel Bisulfate	0		2	(0.1)	2	(0.1)
Acetylsalicylic Acid; Glycine	1	(0.1)	1	(0.1)	2	(0.1)
Dipyridamole	1	(0.1)	1	(0.1)	2	(0.1)
Prasugrel Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Triflusal	1	(0.1)	1	(0.1)	2	(0.1)
Acetylsalicylic Acid; Aluminium Glycinate; Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Acetylsalicylic Acid; Aluminium Hydroxide; Magnesium Hydroxide	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Magnesium Oxide	0		1	(0.1)	1	(0.0)
Beraprost Sodium	0		1	(0.1)	1	(0.0)
Clopidogrel Napadisilate	0		1	(0.1)	1	(0.0)
Clopidogrel Resinate	1	(0.1)	0		1	(0.0)
Salicylic Acid	1	(0.1)	0		1	(0.0)
Salicylic Acid; Urea	0		1	(0.1)	1	(0.0)
Ticlopidine Hydrochloride	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Angiotensin Ii Receptor Blockers (Arbs), Plain, C09ca	574	(26.4)	554	(25.5)	1128	(26.0)
Losartan	179	(8.2)	173	(8.0)	352	(8.1)
Valsartan	84	(3.9)	78	(3.6)	162	(3.7)
Telmisartan	83	(3.8)	77	(3.5)	160	(3.7)
Irbesartan	49	(2.3)	44	(2.0)	93	(2.1)
Candesartan	47	(2.2)	36	(1.7)	83	(1.9)
Losartan Potassium	35	(1.6)	41	(1.9)	76	(1.8)
Candesartan Cilexetil	27	(1.2)	32	(1.5)	59	(1.4)
Olmesartan	26	(1.2)	23	(1.1)	49	(1.1)
Olmesartan Medoxomil	22	(1.0)	26	(1.2)	48	(1.1)
Azilsartan	18	(0.8)	22	(1.0)	40	(0.9)
Allisartan	1	(0.1)	1	(0.1)	2	(0.1)
Azilsartan Medoxomil	2	(0.1)	0		2	(0.1)
Eprosartan	1	(0.1)	1	(0.1)	2	(0.1)
Allisartan Isoproxil	0		1	(0.1)	1	(0.0)
Eprosartan Mesilate	1	(0.1)	0		1	(0.0)
Irbesartan Hydrochloride	1	(0.1)	0		1	(0.0)
Insulin (Human), A10ab01	532	(24.5)	530	(24.4)	1062	(24.5)
Insulin Aspart	335	(15.4)	324	(14.9)	659	(15.2)
Insulin Lispro	194	(8.9)	203	(9.3)	397	(9.2)
Insulin Human	5	(0.2)	4	(0.2)	9	(0.2)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors, A10bh	517	(23.8)	495	(22.8)	1012	(23.3)
Sitagliptin	132	(6.1)	123	(5.7)	255	(5.9)
Vildagliptin	119	(5.5)	118	(5.4)	237	(5.5)
Sitagliptin Phosphate	101	(4.7)	99	(4.6)	200	(4.6)
Linagliptin	76	(3.5)	63	(2.9)	139	(3.2)
Teneligliptin Hydrobromide Hydrate	11	(0.5)	23	(1.1)	34	(0.8)
Teneligliptin	12	(0.6)	16	(0.7)	28	(0.7)
Saxagliptin	11	(0.5)	15	(0.7)	26	(0.6)
Alogliptin Benzoate	13	(0.6)	10	(0.5)	23	(0.5)
Alogliptin	10	(0.5)	7	(0.3)	17	(0.4)
Saxagliptin Hydrochloride	9	(0.4)	5	(0.2)	14	(0.3)
Sitagliptin Phosphate Monohydrate	6	(0.3)	5	(0.2)	11	(0.2)
Anagliptin	5	(0.2)	3	(0.1)	8	(0.2)
Teneligliptin Hydrobromide	3	(0.1)	5	(0.2)	8	(0.2)
Gemigliptin	4	(0.2)	0		4	(0.1)
Gemigliptin Tartrate	1	(0.1)	2	(0.1)	3	(0.1)
Omarigliptin	3	(0.1)	0		3	(0.1)
Evogliptin	1	(0.1)	1	(0.1)	2	(0.1)
Evogliptin Tartrate	1	(0.1)	0		1	(0.0)
Multiple Atc, 0	496	(22.9)	430	(19.8)	926	(21.3)
Multivitamins, Plain	83	(3.8)	60	(2.8)	143	(3.3)
Ascorbic Acid	49	(2.3)	39	(1.8)	88	(2.0)
Sildenafil	21	(1.0)	16	(0.7)	37	(0.8)
Sildenafil Citrate	22	(1.0)	11	(0.5)	33	(0.8)
Zinc	19	(0.9)	13	(0.6)	32	(0.7)
Mecobalamin	20	(0.9)	11	(0.5)	31	(0.7)
Fluticasone	20	(0.9)	10	(0.5)	30	(0.7)
Hyaluronate Sodium	16	(0.7)	14	(0.7)	30	(0.7)
Iron	15	(0.7)	10	(0.5)	25	(0.6)
Tocopherol	16	(0.7)	9	(0.4)	25	(0.6)
Curcuma Longa Rhizome	12	(0.6)	12	(0.6)	24	(0.6)
Vitamins Nos	14	(0.7)	10	(0.5)	24	(0.6)
Potassium	12	(0.6)	11	(0.5)	23	(0.5)
Cinnamomum Verum	6	(0.3)	13	(0.6)	19	(0.4)
Budesonide	8	(0.4)	10	(0.5)	18	(0.4)
Heparinoid	6	(0.3)	10	(0.5)	16	(0.4)
Beclometasone Dipropionate	6	(0.3)	8	(0.4)	14	(0.3)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. 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): NA; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y")
adcm.xpt; variable(s): TRAG1 CMDECOD CMCLAS CMCLASCD; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y") & (SCSTT == "ONGOING AT")
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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Mometasone Furoate	6	(0.3)	7	(0.3)	13	(0.3)
Hydrocortisone	6	(0.3)	6	(0.3)	12	(0.3)
Pyridoxine Hydrochloride	7	(0.3)	5	(0.2)	12	(0.3)
Silybum Marianum	9	(0.4)	3	(0.1)	12	(0.3)
Docusate Sodium	1	(0.1)	10	(0.5)	11	(0.2)
Minerals Nos; Vitamins Nos	4	(0.2)	7	(0.3)	11	(0.2)
Vaccinium Macrocarpon	5	(0.2)	6	(0.3)	11	(0.2)
Aciclovir	5	(0.2)	5	(0.2)	10	(0.2)
Clobetasol Propionate	7	(0.3)	3	(0.1)	10	(0.2)
Formoterol	4	(0.2)	6	(0.3)	10	(0.2)
Glycopyrronium Bromide	1	(0.1)	9	(0.4)	10	(0.2)
Glycyrrhiza Spp. Root; Paeonia Lactiflora Root	6	(0.3)	4	(0.2)	10	(0.2)
Bepotastine Besilate	8	(0.4)	1	(0.1)	9	(0.2)
Brimonidine Tartrate	4	(0.2)	5	(0.2)	9	(0.2)
Fluconazole	7	(0.3)	2	(0.1)	9	(0.2)
Glucosamine	4	(0.2)	5	(0.2)	9	(0.2)
Other Respiratory System Products	5	(0.2)	4	(0.2)	9	(0.2)
Betamethasone Dipropionate	8	(0.4)	0		8	(0.2)
Calcifediol	7	(0.3)	1	(0.1)	8	(0.2)
Ciclesonide	2	(0.1)	6	(0.3)	8	(0.2)
Clotrimazole	5	(0.2)	3	(0.1)	8	(0.2)
Fluticasone Furoate	2	(0.1)	6	(0.3)	8	(0.2)
Hydrocortisone Butyrate	6	(0.3)	2	(0.1)	8	(0.2)
Ketoconazole	6	(0.3)	2	(0.1)	8	(0.2)
Lamotrigine	4	(0.2)	4	(0.2)	8	(0.2)
Terbinafine Hydrochloride	5	(0.2)	3	(0.1)	8	(0.2)
Lidocaine	4	(0.2)	3	(0.1)	7	(0.2)
Nystatin	4	(0.2)	3	(0.1)	7	(0.2)
Triamcinolone	3	(0.1)	4	(0.2)	7	(0.2)
Ascorbic Acid; Betacarotene; Cupric Oxide; Tocopheryl Acetate; Zinc Oxide	2	(0.1)	4	(0.2)	6	(0.1)
Clobetasol	5	(0.2)	1	(0.1)	6	(0.1)
Doxepin	2	(0.1)	4	(0.2)	6	(0.1)
Linum Usitatissimum Seed Oil	4	(0.2)	2	(0.1)	6	(0.1)
Plantago Ovata	3	(0.1)	3	(0.1)	6	(0.1)
Riboflavin	5	(0.2)	1	(0.1)	6	(0.1)
Salmeterol	3	(0.1)	3	(0.1)	6	(0.1)
Selenium	5	(0.2)	1	(0.1)	6	(0.1)
Sulfasalazine	4	(0.2)	2	(0.1)	6	(0.1)
Triamcinolone Acetonide	4	(0.2)	2	(0.1)	6	(0.1)
Urea	2	(0.1)	4	(0.2)	6	(0.1)
Vitamin B12 Nos	3	(0.1)	3	(0.1)	6	(0.1)
Azelastine	1	(0.1)	4	(0.2)	5	(0.1)
Hypromellose	3	(0.1)	2	(0.1)	5	(0.1)
Krill Oil	2	(0.1)	3	(0.1)	5	(0.1)
Meclozine	3	(0.1)	2	(0.1)	5	(0.1)
Metronidazole	3	(0.1)	2	(0.1)	5	(0.1)
Nicotinamide	4	(0.2)	1	(0.1)	5	(0.1)
Prazosin	2	(0.1)	3	(0.1)	5	(0.1)
Probiotics [Umbrella Term]	3	(0.1)	2	(0.1)	5	(0.1)
Tacrolimus	2	(0.1)	3	(0.1)	5	(0.1)
Terbinafine	2	(0.1)	3	(0.1)	5	(0.1)
Allium Sativum	0		4	(0.2)	4	(0.1)
Betamethasone	3	(0.1)	1	(0.1)	4	(0.1)
Betamethasone Butyrate Propionate	3	(0.1)	1	(0.1)	4	(0.1)
Betamethasone Valerate	1	(0.1)	3	(0.1)	4	(0.1)
Calcium; Vitamin D Nos	3	(0.1)	1	(0.1)	4	(0.1)
Carteolol Hydrochloride	1	(0.1)	3	(0.1)	4	(0.1)
Chondroitin Sulfate Sodium	1	(0.1)	3	(0.1)	4	(0.1)
Chondroitin; Glucosamine	1	(0.1)	3	(0.1)	4	(0.1)
Cod-Liver Oil	4	(0.2)	0		4	(0.1)
Docusate	2	(0.1)	2	(0.1)	4	(0.1)
Formoterol Fumarate Dihydrate	4	(0.2)	0		4	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ginkgo Biloba	1	(0.1)	3	(0.1)	4	(0.1)
Hydroxychloroquine	3	(0.1)	1	(0.1)	4	(0.1)
Magnesium Chloride	1	(0.1)	3	(0.1)	4	(0.1)
Methylprednisolone	1	(0.1)	3	(0.1)	4	(0.1)
Methylsulfonylmethane	2	(0.1)	2	(0.1)	4	(0.1)
Pantothenic Acid	4	(0.2)	0		4	(0.1)
Prednisone	3	(0.1)	1	(0.1)	4	(0.1)
Pyridoxine	3	(0.1)	1	(0.1)	4	(0.1)
Retinol	4	(0.2)	0		4	(0.1)
Sucralfate	2	(0.1)	2	(0.1)	4	(0.1)
Terbutaline Sulfate	2	(0.1)	2	(0.1)	4	(0.1)
Azelastine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Betamethasone Valerate; Gentamicin Sulfate	0		3	(0.1)	3	(0.1)
Borneol; Panax Notoginseng Root With Rhizome; Salvia Miltiorrhiza Root With Rhizome	1	(0.1)	2	(0.1)	3	(0.1)
Brimonidine	1	(0.1)	2	(0.1)	3	(0.1)
Caffeine	2	(0.1)	1	(0.1)	3	(0.1)
Calcium Chloride	1	(0.1)	2	(0.1)	3	(0.1)
Cannabidiol	3	(0.1)	0		3	(0.1)
Chromium	2	(0.1)	1	(0.1)	3	(0.1)
Dexamethasone	0		3	(0.1)	3	(0.1)
Fluorometholone	3	(0.1)	0		3	(0.1)
Formoterol Fumarate	0		3	(0.1)	3	(0.1)
Gentamicin Sulfate	1	(0.1)	2	(0.1)	3	(0.1)
Ginkgo Biloba Extract	1	(0.1)	2	(0.1)	3	(0.1)
Glycine Max Seed Oil; Persea Americana Oil	3	(0.1)	0		3	(0.1)
Hydroxocobalamin	3	(0.1)	0		3	(0.1)
Iodine	2	(0.1)	1	(0.1)	3	(0.1)
Ketotifen Fumarate	1	(0.1)	2	(0.1)	3	(0.1)
Lactobacillus Acidophilus	1	(0.1)	2	(0.1)	3	(0.1)
Levosalbutamol	2	(0.1)	1	(0.1)	3	(0.1)
Lysine	3	(0.1)	0		3	(0.1)
Magnesium Aspartate; Potassium Aspartate	1	(0.1)	2	(0.1)	3	(0.1)
Magnesium Citrate	1	(0.1)	2	(0.1)	3	(0.1)
Meclozine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Methadone	3	(0.1)	0		3	(0.1)
Mucopolysaccharide Polysulfuric Acid Ester	1	(0.1)	2	(0.1)	3	(0.1)
Nimesulide	2	(0.1)	1	(0.1)	3	(0.1)
Potassium Citrate	2	(0.1)	1	(0.1)	3	(0.1)
Potassium Iodide	0		3	(0.1)	3	(0.1)
Povidone-Iodine	0		3	(0.1)	3	(0.1)
Procaterol Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Quinine Hydrochloride	3	(0.1)	0		3	(0.1)
Sulpiride	2	(0.1)	1	(0.1)	3	(0.1)
Thyroid	1	(0.1)	2	(0.1)	3	(0.1)
Tranilast	2	(0.1)	1	(0.1)	3	(0.1)
Vaccinium Myrtillus	3	(0.1)	0		3	(0.1)
Vardenafil Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Achyranthes Bidentata Root; Aconitum Spp. Processed Root; Alisma Orientale Tuber; Cinnamomum Cassia Bark; Cornus Officinalis Fruit; Dioscorea Spp. Rhizome; Paeonia X Suffruticosa Root Bark; Plantago Asiatica	2	(0.1)	0		2	(0.1)
Alisma Orientale Tuber; Angelica Acutiloba Root; Atractylodes Lancea Rhizome; Cnidium Officinale Rhizome; Paeonia Lactiflora Root; Poria Cocos Sclerotium	1	(0.1)	1	(0.1)	2	(0.1)
Angelica Acutiloba Root; Astragalus Spp. Root; Atractylodes Lancea Rhizome; Bupleurum Falcatum Root; Cimicifuga Spp. Rhizome; Citrus Aurantium Peel; Glycyrrhiza Spp. Root; Panax Ginseng Root; Zingiber Officin	1	(0.1)	1	(0.1)	2	(0.1)
Angelica Acutiloba Root; Bupleurum Falcatum Root;	0		2	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Cimicifuga Spp. Rhizome; Glycyrrhiza Spp. Root; Rheum Spp. Rhizome; Scutellaria Baicalensis Root						
Beclometasone	1	(0.1)	1	(0.1)	2	(0.1)
Berberine	2	(0.1)	0		2	(0.1)
Betamethasone Sodium Phosphate	1	(0.1)	1	(0.1)	2	(0.1)
Botulinum Toxin Type A	0		2	(0.1)	2	(0.1)
Bupivacaine	0		2	(0.1)	2	(0.1)
Cannabis Sativa	1	(0.1)	1	(0.1)	2	(0.1)
Carbasalate Calcium	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine Maleate	0		2	(0.1)	2	(0.1)
Chondroitin	2	(0.1)	0		2	(0.1)
Chondroitin Sulfate; Glucosamine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Ciprofloxacin	1	(0.1)	1	(0.1)	2	(0.1)
Clarithromycin	0		2	(0.1)	2	(0.1)
Clomipramine	1	(0.1)	1	(0.1)	2	(0.1)
Clomipramine Hydrochloride	0		2	(0.1)	2	(0.1)
Cocos Nucifera Oil	2	(0.1)	0		2	(0.1)
Copper	2	(0.1)	0		2	(0.1)
Cortisone	0		2	(0.1)	2	(0.1)
Cyamopsis Tetragonoloba Gum	2	(0.1)	0		2	(0.1)
Dupilumab	1	(0.1)	1	(0.1)	2	(0.1)
Fenoterol	2	(0.1)	0		2	(0.1)
Fexofenadine Hydrochloride; Pseudoephedrine Hydrochloride	0		2	(0.1)	2	(0.1)
Fluocinonide	1	(0.1)	1	(0.1)	2	(0.1)
Glucosamine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Glycine Max	1	(0.1)	1	(0.1)	2	(0.1)
Glycopyrronium	1	(0.1)	1	(0.1)	2	(0.1)
Guaiazulene	1	(0.1)	1	(0.1)	2	(0.1)
Hydrocortisone Acetate	0		2	(0.1)	2	(0.1)
Hydroxycarbamide	2	(0.1)	0		2	(0.1)
Levofloxacin	1	(0.1)	1	(0.1)	2	(0.1)
Lithium	0		2	(0.1)	2	(0.1)
Macrogol	0		2	(0.1)	2	(0.1)
Magnesium Lactate; Pyridoxine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Manganese	2	(0.1)	0		2	(0.1)
Maxacalcitol	1	(0.1)	1	(0.1)	2	(0.1)
Metoclopramide	1	(0.1)	1	(0.1)	2	(0.1)
Metoclopramide Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Mometasone	1	(0.1)	1	(0.1)	2	(0.1)
Morphine	0		2	(0.1)	2	(0.1)
Naftopidil	1	(0.1)	1	(0.1)	2	(0.1)
Naloxone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Nystatin; Triamcinolone	0		2	(0.1)	2	(0.1)
Oenothera Biennis Oil	1	(0.1)	1	(0.1)	2	(0.1)
Ornidazole	0		2	(0.1)	2	(0.1)
Persea Americana	1	(0.1)	1	(0.1)	2	(0.1)
Potassium Aspartate	0		2	(0.1)	2	(0.1)
Prazosin Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Prednisolone Acetate	1	(0.1)	1	(0.1)	2	(0.1)
Prunus Cerasus	1	(0.1)	1	(0.1)	2	(0.1)
Quercetin	1	(0.1)	1	(0.1)	2	(0.1)
Salmeterol Xinafoate	1	(0.1)	1	(0.1)	2	(0.1)
Sambucus Nigra	0		2	(0.1)	2	(0.1)
Serenoa Repens	1	(0.1)	1	(0.1)	2	(0.1)
Sitosterol	0		2	(0.1)	2	(0.1)
Sodium Bicarbonate; Sodium Chloride	1	(0.1)	1	(0.1)	2	(0.1)
Sodium Gualenate Hydrate	1	(0.1)	1	(0.1)	2	(0.1)
Taurine	1	(0.1)	1	(0.1)	2	(0.1)
Tetracycline Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Tretinoin	1	(0.1)	1	(0.1)	2	(0.1)
Trospium	2	(0.1)	0		2	(0.1)
Trospium Chloride	2	(0.1)	0		2	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Abelmoschus Manihot Flower	0		1	(0.1)	1	(0.0)
Acetazolamide	0		1	(0.1)	1	(0.0)
Acetylcarnitine	1	(0.1)	0		1	(0.0)
Acetylcarnitine Hydrochloride	0		1	(0.1)	1	(0.0)
Acetylcysteine	0		1	(0.1)	1	(0.0)
Achillea Millefolium; Rubia Tinctorum Root Tincture; Senna Alexandrina Fruit; Senna Alexandrina Leaf; Taraxacum Officinale	1	(0.1)	0		1	(0.0)
Aconitum Spp. Processed Root; Alisma Orientale Tuber; Cinnamomum Cassia Bark; Cornus Officinalis Fruit; Dioscorea Spp. Rhizome; Paeonia X Suffruticosa Root Bark; Poria Cocos Sclerotium; Rehmannia Glutinosa R	0		1	(0.1)	1	(0.0)
Aconitum Spp. Processed Root; Atractylodes Lancea Rhizome; Cinnamomum Cassia Bark; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	0		1	(0.1)	1	(0.0)
Ademetionine	1	(0.1)	0		1	(0.0)
Alclometasone Dipropionate	0		1	(0.1)	1	(0.0)
Alisma Orientale Tuber; Atractylodes Lancea Rhizome; Cinnamomum Cassia Bark; Polyporus Umbellatus Sclerotium; Poria Cocos Sclerotium	1	(0.1)	0		1	(0.0)
All Other Therapeutic Products	1	(0.1)	0		1	(0.0)
Allium Sativum Extract	1	(0.1)	0		1	(0.0)
Allium Sativum Oil	0		1	(0.1)	1	(0.0)
Althaea Officinalis Extract; Arctium Lappa Extract; Echinacea Angustifolia Extract; Eucalyptus Globulus Extract; Hydrastis Canadensis Extract; Petroselinum Crispum Extract; Trigonella Foenum-Graecum Extract	0		1	(0.1)	1	(0.0)
Ambroxol	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Asparagus Cochinchinensis Tuber; Bambusa Spp. Trunk; Citrus Aurantium Peel; Fritillaria Thunbergii Bulb; Gardenia Jasminoides Fruit; Glycyrrhiza Spp. Root; Morus Alba Root Bark; Ophio	0		1	(0.1)	1	(0.0)
Angelica Acutiloba Root; Atractylodes Lancea Rhizome; Bupleurum Falcatum Root; Gardenia Jasminoides Fruit; Glycyrrhiza Spp. Root; Mentha Canadensis Herb; Paeonia Lactiflora Root; Paeonia X Suffruticosa Root	0		1	(0.1)	1	(0.0)
Angelica Archangelica Root; Carum Carvi Fruit; Chelidonium Majus Herb; Glycyrrhiza Glabra Root; Iberis Amara; Matricaria Recutita Flower; Melissa Officinalis Leaf; Mentha X Piperita Leaf; Silybum Marianum Fru	0		1	(0.1)	1	(0.0)
Angelica Sinensis; Ligusticum Chuanxiong	1	(0.1)	0		1	(0.0)
Arginine Hydrochloride	1	(0.1)	0		1	(0.0)
Artemisia Argyi Leaf	0		1	(0.1)	1	(0.0)
Asarum Spp. Root; Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Pinellia Ternata Tuber; Schisandra Chinensis Fruit; Zingiber Officinale Rhizome	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Bioflavonoids Nos; Choline Bitartrate; Dl-Methionine; Hydroxocobalamin; Inositol; Nicotinamide; Panthenol; Pyridoxine; Riboflavin; Thiamine	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Colecalciferol; Herbal Nos; Retinol Palmitate; Sambucus Nigra; Sodium; Tocopheryl Acetate; Zinc Citrate	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Ferrous Fumarate	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Ferrous Sulfate	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ascorbic Acid; Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Vaccinium Macrocarpon	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Zinc	0		1	(0.1)	1	(0.0)
Azithromycin	1	(0.1)	0		1	(0.0)
Benzyl Nicotinate	1	(0.1)	0		1	(0.0)
Berberine Hydrochloride; Rheum Spp. Root With Rhizome; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Borneol; Boswellia Sacra Resin; Centipede; Cicada Slough; Dalbergia Odorifera; Eupolyphaga Steleophaga; Leech; Mesobuthus Martensii; Paeonia Spp. Root; Panax Ginseng Root; Santalum Album Heartwood; Ziziphus Juju	1	(0.1)	0		1	(0.0)
Boswellia Serrata	0		1	(0.1)	1	(0.0)
Boswellia Serrata; Bromelains; Curcuma Longa Rhizome; Magnesium Citrate; Piperine; Quercetin Dihydrate	1	(0.1)	0		1	(0.0)
Buprenorphine	1	(0.1)	0		1	(0.0)
Buprenorphine Hydrochloride; Naloxone Hydrochloride	0		1	(0.1)	1	(0.0)
Cabergoline	0		1	(0.1)	1	(0.0)
Calcium; Magnesium; Vitamin D Nos	0		1	(0.1)	1	(0.0)
Camellia Sinensis Leaf	1	(0.1)	0		1	(0.0)
Cannabis Sativa Fruit; Citrus Spp. Unripe Fruit; Magnolia Spp. Bark; Paeonia Lactiflora Root; Prunus Spp. Seed; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Carbomer	1	(0.1)	0		1	(0.0)
Carmellose Sodium	0		1	(0.1)	1	(0.0)
Carnosine	1	(0.1)	0		1	(0.0)
Carteolol	1	(0.1)	0		1	(0.0)
Centella Asiatica Extract	0		1	(0.1)	1	(0.0)
Chlorella Spp.; Plantago Ovata Seed Husk; Spirulina Spp.	0		1	(0.1)	1	(0.0)
Chloride	1	(0.1)	0		1	(0.0)
Choline; Inositol	0		1	(0.1)	1	(0.0)
Chondroitin Sulfate; Glucosamine	1	(0.1)	0		1	(0.0)
Cimicifuga Racemosa	0		1	(0.1)	1	(0.0)
Cimicifuga Racemosa Extract	1	(0.1)	0		1	(0.0)
Cinnamomum Cassia Bark; Cnidium Officinale Rhizome; Glycyrrhiza Spp. Root; Nuphar Japonica Rhizome; Quercus Spp. Bark; Rheum Spp. Rhizome; Syzygium Aromaticum Flower Bud	1	(0.1)	0		1	(0.0)
Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Pueraria Lobata Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	0		1	(0.1)	1	(0.0)
Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Prunus Spp. Seed	1	(0.1)	0		1	(0.0)
Clenbuterol Hydrochloride	1	(0.1)	0		1	(0.0)
Clindamycin	0		1	(0.1)	1	(0.0)
Clindamycin Phosphate	0		1	(0.1)	1	(0.0)
Clioquinol	1	(0.1)	0		1	(0.0)
Clobetasone Butyrate	0		1	(0.1)	1	(0.0)
Collagen	1	(0.1)	0		1	(0.0)
Colostrum	0		1	(0.1)	1	(0.0)
Cromoglicate Sodium	0		1	(0.1)	1	(0.0)
Cromoglicic Acid	1	(0.1)	0		1	(0.0)
Curcuma Longa	1	(0.1)	0		1	(0.0)
Curcuma Longa Rhizome; Tamarindus Indica Seed	1	(0.1)	0		1	(0.0)
Curcuma Zedoaria; Laminaria Japonica	0		1	(0.1)	1	(0.0)
Cyclizine	1	(0.1)	0		1	(0.0)
Dexpanthenol	1	(0.1)	0		1	(0.0)
Dextran	0		1	(0.1)	1	(0.0)
Difluprednate	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dimenhydrinate	0		1	(0.1)	1	(0.0)
Dimetindene Maleate	0		1	(0.1)	1	(0.0)
Doxepin Hydrochloride	0		1	(0.1)	1	(0.0)
Doxylamine Succinate	0		1	(0.1)	1	(0.0)
Echinacea Purpurea	1	(0.1)	0		1	(0.0)
Elastase	1	(0.1)	0		1	(0.0)
Enzymes Nos	0		1	(0.1)	1	(0.0)
Etofenamate	1	(0.1)	0		1	(0.0)
Etretinate	1	(0.1)	0		1	(0.0)
Famciclovir	1	(0.1)	0		1	(0.0)
Fenoterol Hydrobromide	1	(0.1)	0		1	(0.0)
Ferric Hydroxide Polymaltose	1	(0.1)	0		1	(0.0)
Ferrous Sulfate; Vitamins Nos	1	(0.1)	0		1	(0.0)
Fludrocortisone	1	(0.1)	0		1	(0.0)
Flunisolide	1	(0.1)	0		1	(0.0)
Fluocinolone Acetonide	0		1	(0.1)	1	(0.0)
Folinic Acid	1	(0.1)	0		1	(0.0)
Glycerol	0		1	(0.1)	1	(0.0)
Glycerol; Propylene Glycol	0		1	(0.1)	1	(0.0)
Glycine Max Seed Oil	0		1	(0.1)	1	(0.0)
Glycyrrhiza Glabra Root	1	(0.1)	0		1	(0.0)
Glycyrrhiza Spp. Root; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Gramicidin; Neomycin; Nystatin; Triamcinolone	1	(0.1)	0		1	(0.0)
Herbal Nos; Minerals Nos; Vitamins Nos	0		1	(0.1)	1	(0.0)
Herbal Pollen Nos	1	(0.1)	0		1	(0.0)
Hydrocortisone; Oxytetracycline; Polymyxin B	1	(0.1)	0		1	(0.0)
Immunotherapy	1	(0.1)	0		1	(0.0)
Inositol	1	(0.1)	0		1	(0.0)
Iron Polysaccharide Complex	1	(0.1)	0		1	(0.0)
Isoconazole	1	(0.1)	0		1	(0.0)
Lactobacillus Nos	1	(0.1)	0		1	(0.0)
Lecithin	1	(0.1)	0		1	(0.0)
Leuprorelin	0		1	(0.1)	1	(0.0)
Levothyroxine Sodium; Potassium Iodide	1	(0.1)	0		1	(0.0)
Lidocaine Hydrochloride	1	(0.1)	0		1	(0.0)
Linum Usitatissimum Seed	1	(0.1)	0		1	(0.0)
Liver Extract	0		1	(0.1)	1	(0.0)
Lycopene	1	(0.1)	0		1	(0.0)
Macrocystis Pyrifera	1	(0.1)	0		1	(0.0)
Macrogol 400	1	(0.1)	0		1	(0.0)
Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Magnesium Hydrogen Aspartate; Potassium Aspartate	0		1	(0.1)	1	(0.0)
Magnesium Phosphate	1	(0.1)	0		1	(0.0)
Matricaria Recutita	1	(0.1)	0		1	(0.0)
Mephenoxalone	0		1	(0.1)	1	(0.0)
Mepyramine Maleate	1	(0.1)	0		1	(0.0)
Methyl Salicylate	0		1	(0.1)	1	(0.0)
Methylcellulose	1	(0.1)	0		1	(0.0)
Methylprednisolone; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Miconazole	1	(0.1)	0		1	(0.0)
Miconazole Nitrate	1	(0.1)	0		1	(0.0)
Monascus Purpureus	1	(0.1)	0		1	(0.0)
Moringa Oleifera	1	(0.1)	0		1	(0.0)
Moxifloxacin	0		1	(0.1)	1	(0.0)
Mupirocin	0		1	(0.1)	1	(0.0)
Muscle Relaxants	0		1	(0.1)	1	(0.0)
Naloxone	1	(0.1)	0		1	(0.0)
Naloxone Hydrochloride; Tilidine Hydrochloride	1	(0.1)	0		1	(0.0)
Naphazoline Hydrochloride; Pheniramine Maleate	0		1	(0.1)	1	(0.0)
Neticonazole Hydrochloride	1	(0.1)	0		1	(0.0)
Nitric Oxide	0		1	(0.1)	1	(0.0)
Nutrients Nos	0		1	(0.1)	1	(0.0)
Ononis Spinosa Root Extract; Orthosiphon	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Aristatus Leaf Extract; Solidago Virgaurea Herb Extract						
Orphenadrine	1	(0.1)	0		1	(0.0)
Oryzanol	1	(0.1)	0		1	(0.0)
Other Cardiac Preparations	0		1	(0.1)	1	(0.0)
Other Dermatological Preparations	1	(0.1)	0		1	(0.0)
Other Ophthalmologicals	0		1	(0.1)	1	(0.0)
Oxiconazole	1	(0.1)	0		1	(0.0)
Oxygen	1	(0.1)	0		1	(0.0)
Oxymetazoline Hydrochloride	0		1	(0.1)	1	(0.0)
Papain	0		1	(0.1)	1	(0.0)
Paraffin; Wool Fat	0		1	(0.1)	1	(0.0)
Pentosan Polysulfate Sodium	1	(0.1)	0		1	(0.0)
Phleum Pratense Pollen	1	(0.1)	0		1	(0.0)
Phosphorus	1	(0.1)	0		1	(0.0)
Pilocarpine Hydrochloride	0		1	(0.1)	1	(0.0)
Plantago Afra	1	(0.1)	0		1	(0.0)
Plantago Psyllium	1	(0.1)	0		1	(0.0)
Polaprezinc	1	(0.1)	0		1	(0.0)
Polyene Phosphatidylcholine	0		1	(0.1)	1	(0.0)
Polymyxin B	1	(0.1)	0		1	(0.0)
Potassium Citrate; Sodium Citrate Dihydrate	1	(0.1)	0		1	(0.0)
Povidone	1	(0.1)	0		1	(0.0)
Prasterone	1	(0.1)	0		1	(0.0)
Propylene Glycol	1	(0.1)	0		1	(0.0)
Prunus Africana Extract	1	(0.1)	0		1	(0.0)
Quinidine	1	(0.1)	0		1	(0.0)
Quinine Sulfate	0		1	(0.1)	1	(0.0)
Rhamnus Cathartica; Rhamnus Purshiana; Senna Spp.	1	(0.1)	0		1	(0.0)
Rhodiola Rosea	1	(0.1)	0		1	(0.0)
Rifaximin	1	(0.1)	0		1	(0.0)
Saccharated Iron Oxide	1	(0.1)	0		1	(0.0)
Sea Water	0		1	(0.1)	1	(0.0)
Senna Alexandrina	1	(0.1)	0		1	(0.0)
Serenoa Repens Extract; Urtica Dioica Extract	1	(0.1)	0		1	(0.0)
Serenoa Repens Fruit	1	(0.1)	0		1	(0.0)
Sertaconazole Nitrate	1	(0.1)	0		1	(0.0)
Sodium Alginate	0		1	(0.1)	1	(0.0)
Sodium Bicarbonate	1	(0.1)	0		1	(0.0)
Sodium Chloride	1	(0.1)	0		1	(0.0)
Sodium Gualenate	0		1	(0.1)	1	(0.0)
Sulfacetamide Sodium	1	(0.1)	0		1	(0.0)
Sulfadiazine Silver	1	(0.1)	0		1	(0.0)
Sulfamethoxazole	0		1	(0.1)	1	(0.0)
Tacrolimus Monohydrate	1	(0.1)	0		1	(0.0)
Thalidomide	0		1	(0.1)	1	(0.0)
Tocopheryl Acetate	0		1	(0.1)	1	(0.0)
Tolperisone Hydrochloride	1	(0.1)	0		1	(0.0)
Tribenoside	0		1	(0.1)	1	(0.0)
Trifolium Pratense	1	(0.1)	0		1	(0.0)
Trigonella Foenum-Graecum	1	(0.1)	0		1	(0.0)
Troxerutin	1	(0.1)	0		1	(0.0)
Vaccinium Myrtillus Extract	1	(0.1)	0		1	(0.0)
Vaccinium Spp.	0		1	(0.1)	1	(0.0)
Valproate Semisodium	1	(0.1)	0		1	(0.0)
Vitamin E Nos	1	(0.1)	0		1	(0.0)
Vitis Vinifera Seed	0		1	(0.1)	1	(0.0)
Withania Somnifera	1	(0.1)	0		1	(0.0)
Zinc Sulfate	1	(0.1)	0		1	(0.0)
Zingiber Officinale Rhizome	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Beta Blocking Agents, Selective, C07ab	479	(22.1)	441	(20.3)	920	(21.2)
Bisoprolol	95	(4.4)	101	(4.7)	196	(4.5)
Metoprolol	96	(4.4)	92	(4.2)	188	(4.3)
Bisoprolol Fumarate	91	(4.2)	78	(3.6)	169	(3.9)
Atenolol	45	(2.1)	33	(1.5)	78	(1.8)
Metoprolol Succinate	39	(1.8)	37	(1.7)	76	(1.8)
Nebivolol Hydrochloride	42	(1.9)	33	(1.5)	75	(1.7)
Nebivolol	37	(1.7)	31	(1.4)	68	(1.6)
Metoprolol Tartrate	22	(1.0)	23	(1.1)	45	(1.0)
Betaxolol Hydrochloride	6	(0.3)	13	(0.6)	19	(0.4)
Betaxolol	5	(0.2)	1	(0.1)	6	(0.1)
Celiprolol Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Beta Blocking Agents	1	(0.1)	0		1	(0.0)
Dihydropyridine Derivatives, C08ca	446	(20.6)	412	(19.0)	858	(19.8)
Amlodipine	273	(12.6)	270	(12.4)	543	(12.5)
Amlodipine Besilate	90	(4.2)	75	(3.5)	165	(3.8)
Nifedipine	28	(1.3)	24	(1.1)	52	(1.2)
Lercanidipine Hydrochloride	12	(0.6)	7	(0.3)	19	(0.4)
Lercanidipine	15	(0.7)	3	(0.1)	18	(0.4)
Felodipine	5	(0.2)	4	(0.2)	9	(0.2)
Cilnidipine	3	(0.1)	5	(0.2)	8	(0.2)
Lacidipine	7	(0.3)	1	(0.1)	8	(0.2)
Azelnidipine	2	(0.1)	4	(0.2)	6	(0.1)
Benidipine Hydrochloride	3	(0.1)	3	(0.1)	6	(0.1)
Nitrendipine	0		6	(0.3)	6	(0.1)
Manidipine	3	(0.1)	2	(0.1)	5	(0.1)
Levamlodipine Besilate	2	(0.1)	1	(0.1)	3	(0.1)
Manidipine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Amlodipine Maleate	0		2	(0.1)	2	(0.1)
Barnidipine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Nicardipine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Camsilate	0		1	(0.1)	1	(0.0)
Efonidipine Hydrochloride	0		1	(0.1)	1	(0.0)
Nimodipine	0		1	(0.1)	1	(0.0)
S Amlodipine Nicotinate	1	(0.1)	0		1	(0.0)
Glucagon-Like Peptide-1 (Glp-1) Analogues, A10bj	400	(18.4)	400	(18.4)	800	(18.4)
Dulaglutide	158	(7.3)	146	(6.7)	304	(7.0)
Semaglutide	143	(6.6)	158	(7.3)	301	(6.9)
Liraglutide	86	(4.0)	87	(4.0)	173	(4.0)
Exenatide	12	(0.6)	7	(0.3)	19	(0.4)
Lixisenatide	1	(0.1)	2	(0.1)	3	(0.1)
Proton Pump Inhibitors, A02bc	325	(15.0)	304	(14.0)	629	(14.5)
Omeprazole	121	(5.6)	115	(5.3)	236	(5.4)
Pantoprazole Sodium Sesquihydrate	78	(3.6)	63	(2.9)	141	(3.2)
Pantoprazole	37	(1.7)	36	(1.7)	73	(1.7)
Lansoprazole	25	(1.1)	26	(1.2)	51	(1.2)
Esomeprazole Magnesium	24	(1.1)	20	(0.9)	44	(1.0)
Esomeprazole	15	(0.7)	14	(0.7)	29	(0.7)
Vonoprazan Fumarate	6	(0.3)	11	(0.5)	17	(0.4)
Rabeprazole Sodium	6	(0.3)	9	(0.4)	15	(0.3)
Dexlansoprazole	8	(0.4)	4	(0.2)	12	(0.3)
Rabeprazole	2	(0.1)	6	(0.3)	8	(0.2)
Pantoprazole Hemimagnesium Hydrate	1	(0.1)	1	(0.1)	2	(0.1)
Pantoprazole Magnesium	1	(0.1)	1	(0.1)	2	(0.1)
Tegoprazan	2	(0.1)	0		2	(0.1)
Esomeprazole Magnesium Trihydrate	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Thyroid Hormones, H03aa	232	(10.7)	259	(11.9)	491	(11.3)
Levothyroxine Sodium	141	(6.5)	162	(7.5)	303	(7.0)
Levothyroxine	89	(4.1)	97	(4.5)	186	(4.3)
Levothyroxine; Liothyronine	2	(0.1)	1	(0.1)	3	(0.1)
Liothyronine Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Liothyronine	0		1	(0.1)	1	(0.0)
Thiazides, Plain, C03aa	258	(11.9)	197	(9.1)	455	(10.5)
Hydrochlorothiazide	251	(11.6)	192	(8.8)	443	(10.2)
Bendroflumethiazide	5	(0.2)	4	(0.2)	9	(0.2)
Trichlormethiazide	2	(0.1)	1	(0.1)	3	(0.1)
Vitamin D And Analogues, A11cc	238	(11.0)	207	(9.5)	445	(10.2)
Colecalciferol	139	(6.4)	112	(5.2)	251	(5.8)
Vitamin D Nos	88	(4.1)	76	(3.5)	164	(3.8)
Ergocalciferol	9	(0.4)	10	(0.5)	19	(0.4)
Colecalciferol-Cholesterin	3	(0.1)	4	(0.2)	7	(0.2)
Alfacalcidol	1	(0.1)	4	(0.2)	5	(0.1)
Eldecalcitol	1	(0.1)	2	(0.1)	3	(0.1)
Other Lipid Modifying Agents, C10ax	211	(9.7)	194	(8.9)	405	(9.3)
Ezetimibe	121	(5.6)	95	(4.4)	216	(5.0)
Fish Oil	57	(2.6)	54	(2.5)	111	(2.6)
Eicosapentaenoic Acid Ethyl Ester	21	(1.0)	24	(1.1)	45	(1.0)
Omega-3-Acid Ethyl Ester	10	(0.5)	10	(0.5)	20	(0.5)
Evolocumab	2	(0.1)	8	(0.4)	10	(0.2)
Omega-3 Fatty Acids	4	(0.2)	5	(0.2)	9	(0.2)
Eicosapentaenoic Acid	3	(0.1)	0		3	(0.1)
Astaxanthin; Berberine; Folic Acid; Monascus Purpureus; Policosanol; Ubidecarenone	0		2	(0.1)	2	(0.1)
Omega-3 Triglycerides	1	(0.1)	1	(0.1)	2	(0.1)
Alirocumab	1	(0.1)	0		1	(0.0)
Colecalciferol; Fish Oil	0		1	(0.1)	1	(0.0)
Docosahexaenoic Acid; Eicosapentaenoic Acid; Fish Oil	1	(0.1)	0		1	(0.0)
Fish Oil; Krill Oil	0		1	(0.1)	1	(0.0)
Fish Oil; Omega-3 Fatty Acids	1	(0.1)	0		1	(0.0)
Fish Oil; Tocopherol	0		1	(0.1)	1	(0.0)
Linolenic Acid	1	(0.1)	0		1	(0.0)
Omega 9 Fatty Acids	0		1	(0.1)	1	(0.0)
Omega 9 Fatty Acids; Omega-3 Fatty Acids; Omega-6 Fatty Acids	0		1	(0.1)	1	(0.0)
Probucol	1	(0.1)	0		1	(0.0)
Fibrates, C10ab	151	(7.0)	174	(8.0)	325	(7.5)
Fenofibrate	106	(4.9)	128	(5.9)	234	(5.4)
Bezafibrate	24	(1.1)	19	(0.9)	43	(1.0)
Pemafibrate	5	(0.2)	13	(0.6)	18	(0.4)
Gemfibrozil	10	(0.5)	7	(0.3)	17	(0.4)
Ciprofibrate	4	(0.2)	4	(0.2)	8	(0.2)
Fenofibric Acid	1	(0.1)	3	(0.1)	4	(0.1)
Choline Fenofibrate	1	(0.1)	0		1	(0.0)
Sulfonamides, Plain, C03ba	135	(6.2)	141	(6.5)	276	(6.4)
Indapamide	125	(5.8)	128	(5.9)	253	(5.8)
Chlortalidone	9	(0.4)	12	(0.6)	21	(0.5)
Clopamide	2	(0.1)	1	(0.1)	3	(0.1)
Metolazone	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Selective Serotonin Reuptake Inhibitors, N06ab	132	(6.1)	108	(5.0)	240	(5.5)
Escitalopram Oxalate	25	(1.1)	16	(0.7)	41	(0.9)
Citalopram	20	(0.9)	18	(0.8)	38	(0.9)
Escitalopram	23	(1.1)	14	(0.7)	37	(0.8)
Sertraline	11	(0.5)	17	(0.8)	28	(0.7)
Fluoxetine	14	(0.7)	7	(0.3)	21	(0.5)
Fluoxetine Hydrochloride	8	(0.4)	10	(0.5)	18	(0.4)
Sertraline Hydrochloride	14	(0.7)	4	(0.2)	18	(0.4)
Paroxetine	9	(0.4)	5	(0.2)	14	(0.3)
Citalopram Hydrobromide	3	(0.1)	9	(0.4)	12	(0.3)
Paroxetine Hydrochloride	5	(0.2)	3	(0.1)	8	(0.2)
Fluvoxamine Maleate	0		4	(0.2)	4	(0.1)
Fluvoxamine	0		1	(0.1)	1	(0.0)
Other Antidepressants, N06ax	108	(5.0)	127	(5.8)	235	(5.4)
Trazodone	16	(0.7)	29	(1.3)	45	(1.0)
Duloxetine	18	(0.8)	22	(1.0)	40	(0.9)
Duloxetine Hydrochloride	15	(0.7)	21	(1.0)	36	(0.8)
Venlafaxine Hydrochloride	15	(0.7)	13	(0.6)	28	(0.7)
Mirtazapine	15	(0.7)	12	(0.6)	27	(0.6)
Venlafaxine	11	(0.5)	16	(0.7)	27	(0.6)
Bupropion	9	(0.4)	12	(0.6)	21	(0.5)
Bupropion Hydrochloride	13	(0.6)	8	(0.4)	21	(0.5)
Trazodone Hydrochloride	5	(0.2)	5	(0.2)	10	(0.2)
Vortioxetine Hydrobromide	1	(0.1)	2	(0.1)	3	(0.1)
Desvenlafaxine	0		2	(0.1)	2	(0.1)
Desvenlafaxine Succinate Monohydrate	1	(0.1)	1	(0.1)	2	(0.1)
Tianeptine Sodium	2	(0.1)	0		2	(0.1)
Agomelatine Urea	0		1	(0.1)	1	(0.0)
Vilazodone Hydrochloride	1	(0.1)	0		1	(0.0)
Vortioxetine	1	(0.1)	0		1	(0.0)
Preparations Inhibiting Uric Acid Production, M04aa	87	(4.0)	112	(5.2)	199	(4.6)
Allopurinol	71	(3.3)	96	(4.4)	167	(3.9)
Febuxostat	14	(0.7)	16	(0.7)	30	(0.7)
Topiroxostat	2	(0.1)	0		2	(0.1)
Propionic Acid Derivatives, M01ae	86	(4.0)	101	(4.7)	187	(4.3)
Ibuprofen	47	(2.2)	52	(2.4)	99	(2.3)
Naproxen	14	(0.7)	13	(0.6)	27	(0.6)
Loxoprofen Sodium Dihydrate	11	(0.5)	11	(0.5)	22	(0.5)
Loxoprofen Sodium	6	(0.3)	9	(0.4)	15	(0.3)
Naproxen Sodium	5	(0.2)	9	(0.4)	14	(0.3)
Ketoprofen	2	(0.1)	4	(0.2)	6	(0.1)
Flurbiprofen	1	(0.1)	1	(0.1)	2	(0.1)
Pranoprofen	1	(0.1)	1	(0.1)	2	(0.1)
Apronal; Caffeine; Ibuprofen	1	(0.1)	0		1	(0.0)
Apronal; Caffeine; Ibuprofen; Magnesium Oxide	1	(0.1)	0		1	(0.0)
Dexibuprofen	0		1	(0.1)	1	(0.0)
Dexketoprofen	0		1	(0.1)	1	(0.0)
Dexketoprofen Trometamol	1	(0.1)	0		1	(0.0)
Esomeprazole; Naproxen	1	(0.1)	0		1	(0.0)
Ibuprofen Lysinate	0		1	(0.1)	1	(0.0)
Ibuprofen Sodium	1	(0.1)	0		1	(0.0)
Ibuprofen; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Thiazolidinediones, A10bg	98	(4.5)	80	(3.7)	178	(4.1)
Pioglitazone	54	(2.5)	54	(2.5)	108	(2.5)
Pioglitazone Hydrochloride	43	(2.0)	26	(1.2)	69	(1.6)
Lobeglitazone Sulfate	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Gabapentin, N03ax12	81	(3.7)	84	(3.9)	165	(3.8)
Gabapentin	81	(3.7)	84	(3.9)	165	(3.8)
Vitamin B12 (Cyanocobalamin And Analogues), B03ba	91	(4.2)	70	(3.2)	161	(3.7)
Cyanocobalamin	82	(3.8)	60	(2.8)	142	(3.3)
Cyanocobalamin-Tannin Complex	2	(0.1)	5	(0.2)	7	(0.2)
Cyanocobalamin; Pyridoxine Hydrochloride; Thiamine Hydrochloride	3	(0.1)	2	(0.1)	5	(0.1)
Cyanocobalamin; Pyridoxine; Thiamine	2	(0.1)	1	(0.1)	3	(0.1)
Cyanocobalamin; Folic Acid	1	(0.1)	0		1	(0.0)
Cyanocobalamin; Folic Acid; Pyridoxine	0		1	(0.1)	1	(0.0)
Folic Acid; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Levomefolic Acid; Mecobalamin; Pyridoxine	1	(0.1)	0		1	(0.0)
Sulfonamides, Plain, C03ca	72	(3.3)	83	(3.8)	155	(3.6)
Furosemide	54	(2.5)	56	(2.6)	110	(2.5)
Torasemide	14	(0.7)	24	(1.1)	38	(0.9)
Bumetanide	2	(0.1)	2	(0.1)	4	(0.1)
Azosemide	1	(0.1)	1	(0.1)	2	(0.1)
Furosemide; Sodium Chloride	1	(0.1)	0		1	(0.0)
Alpha-Adrenoreceptor Antagonists, G04ca	73	(3.4)	81	(3.7)	154	(3.5)
Tamsulosin	23	(1.1)	39	(1.8)	62	(1.4)
Tamsulosin Hydrochloride	26	(1.2)	24	(1.1)	50	(1.1)
Silodosin	8	(0.4)	7	(0.3)	15	(0.3)
Alfuzosin	7	(0.3)	4	(0.2)	11	(0.2)
Alfuzosin Hydrochloride	6	(0.3)	2	(0.1)	8	(0.2)
Terazosin	4	(0.2)	3	(0.1)	7	(0.2)
Terazosin Hydrochloride	0		2	(0.1)	2	(0.1)
Other Antihistamines For Systemic Use, R06ax	70	(3.2)	69	(3.2)	139	(3.2)
Loratadine	35	(1.6)	35	(1.6)	70	(1.6)
Fexofenadine Hydrochloride	8	(0.4)	12	(0.6)	20	(0.5)
Desloratadine	7	(0.3)	5	(0.2)	12	(0.3)
Epinastine Hydrochloride	3	(0.1)	6	(0.3)	9	(0.2)
Olopatadine Hydrochloride	4	(0.2)	5	(0.2)	9	(0.2)
Bilastine	4	(0.2)	3	(0.1)	7	(0.2)
Fexofenadine	3	(0.1)	3	(0.1)	6	(0.1)
Rupatadine Fumarate	5	(0.2)	1	(0.1)	6	(0.1)
Ebastine	2	(0.1)	0		2	(0.1)
Epinastine	1	(0.1)	0		1	(0.0)
Alpha Glucosidase Inhibitors, A10bf	65	(3.0)	70	(3.2)	135	(3.1)
Acarbose	36	(1.7)	38	(1.8)	74	(1.7)
Voglibose	16	(0.7)	21	(1.0)	37	(0.8)
Miglitol	13	(0.6)	11	(0.5)	24	(0.6)
Alpha And Beta Blocking Agents, C07ag	66	(3.0)	67	(3.1)	133	(3.1)
Carvedilol	64	(3.0)	65	(3.0)	129	(3.0)
Arotinolol Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Labetalol	1	(0.1)	1	(0.1)	2	(0.1)
Anilides, N02be	62	(2.9)	71	(3.3)	133	(3.1)
Paracetamol	58	(2.7)	62	(2.9)	120	(2.8)
Acetylsalicylic Acid; Caffeine; Paracetamol	4	(0.2)	2	(0.1)	6	(0.1)
Caffeine; Paracetamol	0		4	(0.2)	4	(0.1)
Apronal; Caffeine; Paracetamol; Propyphenazone	0		2	(0.1)	2	(0.1)
Butalbital; Caffeine; Codeine Phosphate; Paracetamol	0		1	(0.1)	1	(0.0)
Butalbital; Caffeine; Paracetamol	0		1	(0.1)	1	(0.0)
Ibuprofen; Paracetamol	1	(0.1)	0		1	(0.0)
Paracetamol; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Selective Beta-2-Adrenoreceptor Agonists, R03ac	66	(3.0)	66	(3.0)	132	(3.0)
Salbutamol	45	(2.1)	42	(1.9)	87	(2.0)
Salbutamol Sulfate	18	(0.8)	19	(0.9)	37	(0.8)
Vilanterol	5	(0.2)	1	(0.1)	6	(0.1)
Indacaterol	1	(0.1)	1	(0.1)	2	(0.1)
Indacaterol Maleate	0		2	(0.1)	2	(0.1)
Ipratropium Bromide; Salbutamol Sulfate	0		1	(0.1)	1	(0.0)
Olodaterol Hydrochloride	1	(0.1)	0		1	(0.0)
Salmeterol	1	(0.1)	0		1	(0.0)
Vilanterol Trifenatate	0		1	(0.1)	1	(0.0)
Calcium, A12aa	63	(2.9)	43	(2.0)	106	(2.4)
Calcium	38	(1.8)	24	(1.1)	62	(1.4)
Calcium Carbonate	21	(1.0)	15	(0.7)	36	(0.8)
Calcium Citrate	2	(0.1)	2	(0.1)	4	(0.1)
Calcium Carbonate; Vitamin D Nos	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Carbonate; Colecalciferol; Pyridoxine Hydrochloride	1	(0.1)	0		1	(0.0)
Calcium Carbonate; Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Insulins And Analogues For Injection, Fast-Acting, A10ab	50	(2.3)	56	(2.6)	106	(2.4)
Insulin Glulisine	48	(2.2)	54	(2.5)	102	(2.4)
Insulin Lispro Biosimilar 1	1	(0.1)	2	(0.1)	3	(0.1)
Insulin Lispro Aabc	1	(0.1)	0		1	(0.0)
Aldosterone Antagonists, C03da	49	(2.3)	47	(2.2)	96	(2.2)
Spironolactone	42	(1.9)	39	(1.8)	81	(1.9)
Eplerenone	6	(0.3)	8	(0.4)	14	(0.3)
Esaxerenone	1	(0.1)	0		1	(0.0)
Direct Factor Xa Inhibitors, B01af	48	(2.2)	42	(1.9)	90	(2.1)
Apixaban	20	(0.9)	24	(1.1)	44	(1.0)
Rivaroxaban	23	(1.1)	15	(0.7)	38	(0.9)
Edoxaban	3	(0.1)	1	(0.1)	4	(0.1)
Edoxaban Tosilate	2	(0.1)	2	(0.1)	4	(0.1)
Prostaglandin Analogues, S01ee	45	(2.1)	44	(2.0)	89	(2.0)
Latanoprost	26	(1.2)	28	(1.3)	54	(1.2)
Bimatoprost	7	(0.3)	9	(0.4)	16	(0.4)
Travoprost	5	(0.2)	5	(0.2)	10	(0.2)
Tafluprost	5	(0.2)	1	(0.1)	6	(0.1)
Latanoprostene Bunod	2	(0.1)	0		2	(0.1)
Latanoprost; Netarsudil Mesilate	0		1	(0.1)	1	(0.0)
Piperazine Derivatives, R06ae	43	(2.0)	43	(2.0)	86	(2.0)
Cetirizine Hydrochloride	27	(1.2)	21	(1.0)	48	(1.1)
Cetirizine	9	(0.4)	11	(0.5)	20	(0.5)
Levocetirizine Dihydrochloride	6	(0.3)	8	(0.4)	14	(0.3)
Levocetirizine	2	(0.1)	3	(0.1)	5	(0.1)
Benzodiazepine Derivatives, N05ba	38	(1.8)	46	(2.1)	84	(1.9)
Alprazolam	19	(0.9)	15	(0.7)	34	(0.8)
Lorazepam	8	(0.4)	14	(0.7)	22	(0.5)
Diazepam	3	(0.1)	5	(0.2)	8	(0.2)
Etizolam	2	(0.1)	3	(0.1)	5	(0.1)
Oxazepam	1	(0.1)	4	(0.2)	5	(0.1)
Bromazepam	2	(0.1)	2	(0.1)	4	(0.1)
Ethyl Loflazepate	1	(0.1)	2	(0.1)	3	(0.1)
Clotiazepam	0		2	(0.1)	2	(0.1)
Chlordiazepoxide	0		1	(0.1)	1	(0.0)
Medazepam	1	(0.1)	0		1	(0.0)
Mexazolam	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Pregabalin, N03ax16	40	(1.8)	42	(1.9)	82	(1.9)
Pregabalin	40	(1.8)	40	(1.8)	80	(1.8)
Mecobalamin; Pregabalin	0		1	(0.1)	1	(0.0)
Nortriptyline; Pregabalin	0		1	(0.1)	1	(0.0)
Other Cardiac Preparations, C01eb	46	(2.1)	34	(1.6)	80	(1.8)
Ubidecarenone	22	(1.0)	19	(0.9)	41	(0.9)
Trimetazidine Hydrochloride	11	(0.5)	11	(0.5)	22	(0.5)
Ranolazine	7	(0.3)	1	(0.1)	8	(0.2)
Ivabradine	1	(0.1)	2	(0.1)	3	(0.1)
Ivabradine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Adenosine Triphosphate, Disodium Salt	2	(0.1)	0		2	(0.1)
Ivabradine Hydrobromide	1	(0.1)	0		1	(0.0)
Ivabradine Oxalate	0		1	(0.1)	1	(0.0)
Trimetazidine	1	(0.1)	0		1	(0.0)
Various Alimentary Tract And Metabolism Products, A16ax	50	(2.3)	28	(1.3)	78	(1.8)
Thioctic Acid	46	(2.1)	24	(1.1)	70	(1.6)
Folic Acid; Mecobalamin; Pyridoxine Hydrochloride; Thioctic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Antioxidants Nos	1	(0.1)	0		1	(0.0)
Chromium Picolinate; Cinnamomum Cassia Bark	1	(0.1)	0		1	(0.0)
Folic Acid; Mecobalamin; Pregabalin; Pyridoxine Hydrochloride; Thioctic Acid	0		1	(0.1)	1	(0.0)
Mecobalamin; Thioctic Acid	1	(0.1)	0		1	(0.0)
Thioctic Acid Tromethamine	0		1	(0.1)	1	(0.0)
Insulins And Analogues For Injection, Intermediate-Acting, A10ac	36	(1.7)	41	(1.9)	77	(1.8)
Insulin Human Injection, Isophane	31	(1.4)	32	(1.5)	63	(1.4)
Isophane Insulin	5	(0.2)	9	(0.4)	14	(0.3)
Other Blood Glucose Lowering Drugs, Excl. Insulins, A10bx	32	(1.5)	42	(1.9)	74	(1.7)
Repaglinide	19	(0.9)	23	(1.1)	42	(1.0)
Mitiglinide Calcium	8	(0.4)	11	(0.5)	19	(0.4)
Nateglinide	2	(0.1)	6	(0.3)	8	(0.2)
Saroglitazar	1	(0.1)	1	(0.1)	2	(0.1)
Biotin; Chromium; Cinnamomum Spp.	1	(0.1)	0		1	(0.0)
Bromocriptine	0		1	(0.1)	1	(0.0)
Bromocriptine Mesilate	0		1	(0.1)	1	(0.0)
Mitiglinide	1	(0.1)	0		1	(0.0)
Imidazoline Receptor Agonists, C02ac	32	(1.5)	38	(1.8)	70	(1.6)
Moxonidine	19	(0.9)	12	(0.6)	31	(0.7)
Rilmenidine	5	(0.2)	9	(0.4)	14	(0.3)
Clonidine	5	(0.2)	8	(0.4)	13	(0.3)
Clonidine Hydrochloride	2	(0.1)	5	(0.2)	7	(0.2)
Rilmenidine Phosphate	1	(0.1)	4	(0.2)	5	(0.1)
Corticosteroids, R01ad	38	(1.8)	31	(1.4)	69	(1.6)
Fluticasone Propionate	38	(1.8)	30	(1.4)	68	(1.6)
Dexamethasone Cipecilate	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Acetic Acid Derivatives And Related Substances, M01ab	30	(1.4)	38	(1.8)	68	(1.6)
Diclofenac	16	(0.7)	13	(0.6)	29	(0.7)
Diclofenac Sodium	6	(0.3)	7	(0.3)	13	(0.3)
Indometacin	2	(0.1)	8	(0.4)	10	(0.2)
Etodolac	1	(0.1)	4	(0.2)	5	(0.1)
Bromfenac Sodium	0		4	(0.2)	4	(0.1)
Aceclofenac	2	(0.1)	1	(0.1)	3	(0.1)
Diclofenac Potassium	2	(0.1)	0		2	(0.1)
Sulindac	1	(0.1)	1	(0.1)	2	(0.1)
Cyanocobalamin; Diclofenac Sodium; Pyridoxine Hydrochloride; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Diclofenac Diethylamine	1	(0.1)	0		1	(0.0)
Diclofenac Sodium; Misoprostol	0		1	(0.1)	1	(0.0)
Organic Nitrates, C01da	39	(1.8)	27	(1.2)	66	(1.5)
Glyceryl Trinitrate	22	(1.0)	21	(1.0)	43	(1.0)
Isosorbide Mononitrate	19	(0.9)	6	(0.3)	25	(0.6)
Isosorbide	2	(0.1)	3	(0.1)	5	(0.1)
Isosorbide Dinitrate	1	(0.1)	1	(0.1)	2	(0.1)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics, C09da	28	(1.3)	33	(1.5)	61	(1.4)
Hydrochlorothiazide; Losartan Potassium	8	(0.4)	9	(0.4)	17	(0.4)
Hydrochlorothiazide; Telmisartan	7	(0.3)	7	(0.3)	14	(0.3)
Hydrochlorothiazide; Valsartan	4	(0.2)	8	(0.4)	12	(0.3)
Hydrochlorothiazide; Irbesartan	2	(0.1)	3	(0.1)	5	(0.1)
Candesartan Cilexetil; Hydrochlorothiazide	3	(0.1)	1	(0.1)	4	(0.1)
Hydrochlorothiazide; Losartan	0		3	(0.1)	3	(0.1)
Azilsartan Kamedoxomil; Chlortalidone	1	(0.1)	1	(0.1)	2	(0.1)
Hydrochlorothiazide; Olmesartan Medoxomil	1	(0.1)	1	(0.1)	2	(0.1)
Azilsartan Medoxomil; Chlortalidone	1	(0.1)	0		1	(0.0)
Candesartan; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Magnesium, A12cc	39	(1.8)	21	(1.0)	60	(1.4)
Magnesium	36	(1.7)	19	(0.9)	55	(1.3)
Magnesium Aspartate	0		1	(0.1)	1	(0.0)
Magnesium Aspartate Hydrochloride	1	(0.1)	0		1	(0.0)
Magnesium Aspartate; Magnesium Citrate; Magnesium Oxide	1	(0.1)	0		1	(0.0)
Magnesium Malate	0		1	(0.1)	1	(0.0)
Magnesium; Magnesium Carbonate; Magnesium Citrate; Magnesium Phosphate	1	(0.1)	0		1	(0.0)
Benzodiazepine Related Drugs, N05cf	29	(1.3)	29	(1.3)	58	(1.3)
Zolpidem Tartrate	15	(0.7)	14	(0.7)	29	(0.7)
Zolpidem	5	(0.2)	10	(0.5)	15	(0.3)
Zopiclone	6	(0.3)	4	(0.2)	10	(0.2)
Eszopiclone	3	(0.1)	2	(0.1)	5	(0.1)
H2-Receptor Antagonists, A02ba	28	(1.3)	28	(1.3)	56	(1.3)
Famotidine	22	(1.0)	25	(1.1)	47	(1.1)
Ranitidine	4	(0.2)	1	(0.1)	5	(0.1)
Lafutidine	2	(0.1)	2	(0.1)	4	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers, C09db	31	(1.4)	24	(1.1)	55	(1.3)
Amlodipine Besilate; Irbesartan	8	(0.4)	3	(0.1)	11	(0.2)
Amlodipine Besilate; Telmisartan	5	(0.2)	4	(0.2)	9	(0.2)
Amlodipine Besilate; Valsartan	5	(0.2)	4	(0.2)	9	(0.2)
Amlodipine Besilate; Azilsartan	4	(0.2)	4	(0.2)	8	(0.2)
Amlodipine Besilate; Candesartan Cilexetil	4	(0.2)	1	(0.1)	5	(0.1)
Azelnidipine; Olmesartan Medoxomil	1	(0.1)	3	(0.1)	4	(0.1)
Amlodipine Besilate; Olmesartan Medoxomil	1	(0.1)	2	(0.1)	3	(0.1)
Amlodipine; Telmisartan	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine; Valsartan	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine; Olmesartan	1	(0.1)	0		1	(0.0)
Cilnidipine; Telmisartan	0		1	(0.1)	1	(0.0)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics, R03ak	25	(1.1)	29	(1.3)	54	(1.2)
Budesonide; Formoterol Fumarate	10	(0.5)	12	(0.6)	22	(0.5)
Fluticasone Propionate; Salmeterol Xinafoate	4	(0.2)	8	(0.4)	12	(0.3)
Fluticasone Furoate; Vilanterol Trifenatate	5	(0.2)	6	(0.3)	11	(0.2)
Beclometasone Dipropionate; Formoterol Fumarate	2	(0.1)	1	(0.1)	3	(0.1)
Formoterol Fumarate; Mometasone Furoate	1	(0.1)	1	(0.1)	2	(0.1)
Budesonide; Formoterol Fumarate Dihydrate	0		1	(0.1)	1	(0.0)
Cromoglicate Sodium; Reproterol Hydrochloride	0		1	(0.1)	1	(0.0)
Fluticasone Furoate; Vilanterol	1	(0.1)	0		1	(0.0)
Fluticasone Propionate; Formoterol Fumarate	1	(0.1)	0		1	(0.0)
Fluticasone Propionate; Salmeterol	1	(0.1)	0		1	(0.0)
Alpha-Adrenoreceptor Antagonists, C02ca	30	(1.4)	22	(1.0)	52	(1.2)
Doxazosin Mesilate	13	(0.6)	12	(0.6)	25	(0.6)
Doxazosin	12	(0.6)	10	(0.5)	22	(0.5)
Urapidil	6	(0.3)	1	(0.1)	7	(0.2)
Beta Blocking Agents, Non-Selective, C07aa	27	(1.2)	25	(1.1)	52	(1.2)
Propranolol	11	(0.5)	10	(0.5)	21	(0.5)
Timolol	6	(0.3)	8	(0.4)	14	(0.3)
Propranolol Hydrochloride	5	(0.2)	0		5	(0.1)
Sotalol	3	(0.1)	2	(0.1)	5	(0.1)
Sotalol Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Nadolol	0		2	(0.1)	2	(0.1)
Timolol Maleate	1	(0.1)	1	(0.1)	2	(0.1)
Leukotriene Receptor Antagonists, R03dc	23	(1.1)	29	(1.3)	52	(1.2)
Montelukast Sodium	13	(0.6)	18	(0.8)	31	(0.7)
Montelukast	10	(0.5)	10	(0.5)	20	(0.5)
Pranlukast Hydrate	0		1	(0.1)	1	(0.0)
Non-Selective Monoamine Reuptake Inhibitors, N06aa	25	(1.1)	26	(1.2)	51	(1.2)
Amitriptyline	16	(0.7)	11	(0.5)	27	(0.6)
Amitriptyline Hydrochloride	3	(0.1)	5	(0.2)	8	(0.2)
Nortriptyline	4	(0.2)	3	(0.1)	7	(0.2)
Nortriptyline Hydrochloride	0		4	(0.2)	4	(0.1)
Opipramol Hydrochloride	0		2	(0.1)	2	(0.1)
Amoxapine	1	(0.1)	0		1	(0.0)
Imipramine	1	(0.1)	0		1	(0.0)
Opipramol	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Centrally Acting Agents, M03bx	29	(1.3)	21	(1.0)	50	(1.1)
Cyclobenzaprine Hydrochloride	8	(0.4)	5	(0.2)	13	(0.3)
Tizanidine	6	(0.3)	3	(0.1)	9	(0.2)
Tizanidine Hydrochloride	5	(0.2)	4	(0.2)	9	(0.2)
Cyclobenzaprine	4	(0.2)	4	(0.2)	8	(0.2)
Baclofen	3	(0.1)	3	(0.1)	6	(0.1)
Thiocolchicoside	2	(0.1)	1	(0.1)	3	(0.1)
Afloqualone	0		1	(0.1)	1	(0.0)
Eperisone Hydrochloride	1	(0.1)	0		1	(0.0)
Fenyramidol Hydrochloride	1	(0.1)	0		1	(0.0)
Drugs For Urinary Frequency And Incontinence, G04bd	31	(1.4)	18	(0.8)	49	(1.1)
Mirabegron	10	(0.5)	5	(0.2)	15	(0.3)
Oxybutynin	4	(0.2)	4	(0.2)	8	(0.2)
Solifenacin Succinate	3	(0.1)	4	(0.2)	7	(0.2)
Fesoterodine Fumarate	3	(0.1)	1	(0.1)	4	(0.1)
Oxybutynin Hydrochloride	3	(0.1)	1	(0.1)	4	(0.1)
Solifenacin	3	(0.1)	1	(0.1)	4	(0.1)
Vibegron	2	(0.1)	2	(0.1)	4	(0.1)
Tolterodine L-Tartrate	2	(0.1)	0		2	(0.1)
Darifenacin	0		1	(0.1)	1	(0.0)
Flavoxate Hydrochloride	1	(0.1)	0		1	(0.0)
Propiverine Hydrochloride	1	(0.1)	0		1	(0.0)
Folic Acid And Derivatives, B03bb	27	(1.2)	22	(1.0)	49	(1.1)
Folic Acid	27	(1.2)	20	(0.9)	47	(1.1)
Calcium; Calcium Ascorbate; Calcium L-Threonate; Colecalciferol; Docosahexaenoic Acid; Eicosapentaenoic Acid; Ferrous Asparto Glycinate; Folic Acid; Iron; Linolenic Acid; Pyridoxine Hydrochloride; Tocopheryl Ace	0		1	(0.1)	1	(0.0)
Folic Acid; Vitamins Nos	0		1	(0.1)	1	(0.0)
Natural And Semisynthetic Estrogens, Plain, G03ca	19	(0.9)	28	(1.3)	47	(1.1)
Estradiol	11	(0.5)	12	(0.6)	23	(0.5)
Ethinylestradiol	3	(0.1)	6	(0.3)	9	(0.2)
Estrogens Conjugated	4	(0.2)	4	(0.2)	8	(0.2)
Estriol	0		2	(0.1)	2	(0.1)
Calcium Levomefolate; Drospirenone; Ethinylestradiol	0		1	(0.1)	1	(0.0)
Dienogest; Estradiol Valerate	0		1	(0.1)	1	(0.0)
Dydrogesterone; Estradiol	0		1	(0.1)	1	(0.0)
Dydrogesterone; Estradiol Hemihydrate	1	(0.1)	0		1	(0.0)
Estradiol; Estriol	0		1	(0.1)	1	(0.0)
Estradiol; Nomegestrol Acetate	0		1	(0.1)	1	(0.0)
Estradiol; Norethisterone	1	(0.1)	0		1	(0.0)
3-Oxoandrosten (4) Derivatives, G03ba	26	(1.2)	20	(0.9)	46	(1.1)
Testosterone	19	(0.9)	11	(0.5)	30	(0.7)
Testosterone Cipionate	6	(0.3)	5	(0.2)	11	(0.2)
Testosterone Undecanoate	1	(0.1)	3	(0.1)	4	(0.1)
Methyltestosterone	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Beta Blocking Agents, S01ed	28	(1.3)	18	(0.8)	46	(1.1)
Dorzolamide Hydrochloride; Timolol Maleate	9	(0.4)	10	(0.5)	19	(0.4)
Brimonidine Tartrate; Timolol Maleate	3	(0.1)	3	(0.1)	6	(0.1)
Latanoprost; Timolol Maleate	5	(0.2)	1	(0.1)	6	(0.1)
Tafluprost; Timolol Maleate	1	(0.1)	2	(0.1)	3	(0.1)
Timolol Maleate; Travoprost	3	(0.1)	0		3	(0.1)
Bimatoprost; Timolol Maleate	2	(0.1)	0		2	(0.1)
Brinzolamide; Timolol Maleate	0		2	(0.1)	2	(0.1)
Timolol; Travoprost	2	(0.1)	0		2	(0.1)
Brimonidine; Timolol	1	(0.1)	0		1	(0.0)
Brinzolamide; Timolol	1	(0.1)	0		1	(0.0)
Dorzolamide Hydrochloride; Timolol	1	(0.1)	0		1	(0.0)
Magnesium Compounds, A02aa	20	(0.9)	26	(1.2)	46	(1.1)
Magnesium Oxide	17	(0.8)	16	(0.7)	33	(0.8)
Magnesium Hydroxide	3	(0.1)	9	(0.4)	12	(0.3)
Magnesium Carbonate; Magnesium Oxide	0		1	(0.1)	1	(0.0)
Progestogens, G03ac	21	(1.0)	23	(1.1)	44	(1.0)
Desogestrel	7	(0.3)	4	(0.2)	11	(0.2)
Levonorgestrel	5	(0.2)	5	(0.2)	10	(0.2)
Norethisterone	3	(0.1)	2	(0.1)	5	(0.1)
Medroxyprogesterone Acetate	0		4	(0.2)	4	(0.1)
Ethinylestradiol; Levonorgestrel	0		3	(0.1)	3	(0.1)
Etonogestrel	2	(0.1)	1	(0.1)	3	(0.1)
Drospirenone	1	(0.1)	1	(0.1)	2	(0.1)
Ethinylestradiol; Ferrous Fumarate; Norethisterone Acetate	1	(0.1)	1	(0.1)	2	(0.1)
Ethinylestradiol; Norethisterone Acetate	1	(0.1)	1	(0.1)	2	(0.1)
Estrogens Conjugated; Medroxyprogesterone Acetate	1	(0.1)	0		1	(0.0)
Ethinylestradiol; Norethisterone	0		1	(0.1)	1	(0.0)
Tadalafil, G04be08	20	(0.9)	24	(1.1)	44	(1.0)
Tadalafil	20	(0.9)	24	(1.1)	44	(1.0)
Vitamin K Antagonists, B01aa	26	(1.2)	18	(0.8)	44	(1.0)
Warfarin	12	(0.6)	9	(0.4)	21	(0.5)
Acenocoumarol	9	(0.4)	1	(0.1)	10	(0.2)
Warfarin Sodium	3	(0.1)	5	(0.2)	8	(0.2)
Phenprocoumon	1	(0.1)	3	(0.1)	4	(0.1)
Warfarin Potassium	1	(0.1)	0		1	(0.0)
Testosterone-5-Alpha Reductase Inhibitors, G04cb	23	(1.1)	19	(0.9)	42	(1.0)
Finasteride	17	(0.8)	11	(0.5)	28	(0.7)
Dutasteride	6	(0.3)	8	(0.4)	14	(0.3)
Other Ophthalmologicals, S01xa	20	(0.9)	21	(1.0)	41	(0.9)
Pirenoxine	4	(0.2)	6	(0.3)	10	(0.2)
Diquafosol Tetrasodium	3	(0.1)	4	(0.2)	7	(0.2)
Xantofyl	4	(0.2)	2	(0.1)	6	(0.1)
Xantofyl; Zeaxanthin	2	(0.1)	3	(0.1)	5	(0.1)
Ascorbic Acid; Cupric Oxide; Dl-Alpha Tocopheryl Acetate; Xantofyl; Zeaxanthin; Zinc Oxide	3	(0.1)	1	(0.1)	4	(0.1)
Macrogol 400; Propylene Glycol	0		3	(0.1)	3	(0.1)
Pirenoxine Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Ascorbic Acid; Tocopheryl Acetate; Xantofyl; Zeaxanthin; Zinc	1	(0.1)	0		1	(0.0)
Diquafosol	1	(0.1)	0		1	(0.0)
Polyvinyl Alcohol	1	(0.1)	0		1	(0.0)
Zeaxanthin	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ace Inhibitors And Diuretics, C09ba	17	(0.8)	22	(1.0)	39	(0.9)
Indapamide; Perindopril Erbumine	4	(0.2)	6	(0.3)	10	(0.2)
Hydrochlorothiazide; Lisinopril	3	(0.1)	5	(0.2)	8	(0.2)
Indapamide; Perindopril Arginine	3	(0.1)	5	(0.2)	8	(0.2)
Enalapril Maleate; Hydrochlorothiazide	1	(0.1)	2	(0.1)	3	(0.1)
Indapamide; Perindopril	2	(0.1)	1	(0.1)	3	(0.1)
Indapamide; Perindopril Tosilate	1	(0.1)	2	(0.1)	3	(0.1)
Hydrochlorothiazide; Ramipril	1	(0.1)	1	(0.1)	2	(0.1)
Hydrochlorothiazide; Lisinopril Dihydrate	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Zofenopril Calcium	1	(0.1)	0		1	(0.0)
Iron Bivalent, Oral Preparations, B03aa	16	(0.7)	20	(0.9)	36	(0.8)
Ferrous Sulfate	9	(0.4)	11	(0.5)	20	(0.5)
Ferrous Fumarate	5	(0.2)	3	(0.1)	8	(0.2)
Ferrous Sodium Citrate	1	(0.1)	4	(0.2)	5	(0.1)
Ferrous Gluconate	1	(0.1)	2	(0.1)	3	(0.1)
Oxicams, M01ac	20	(0.9)	16	(0.7)	36	(0.8)
Meloxicam	19	(0.9)	16	(0.7)	35	(0.8)
Ampiroxicam	1	(0.1)	0		1	(0.0)
Potassium, A12ba	18	(0.8)	18	(0.8)	36	(0.8)
Potassium Chloride	17	(0.8)	18	(0.8)	35	(0.8)
Boric Acid; Potassium Chloride; Sodium Carbonate Anhydrous; Sodium Chloride; Sodium Phosphate Dibasic	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Plain, A11ea	16	(0.7)	18	(0.8)	34	(0.8)
Vitamin B Complex	13	(0.6)	18	(0.8)	31	(0.7)
Vitamin B-Complex, Plain	2	(0.1)	0		2	(0.1)
Calcium Pantothenate; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Mononitrate	1	(0.1)	0		1	(0.0)
Calcium, Combinations With Vitamin D And/Or Other Drugs, A12ax	14	(0.7)	19	(0.9)	33	(0.8)
Calcium Carbonate; Colecalciferol	5	(0.2)	9	(0.4)	14	(0.3)
Calcium; Colecalciferol	5	(0.2)	3	(0.1)	8	(0.2)
Calcium Carbonate; Colecalciferol; Menaquinone	0		2	(0.1)	2	(0.1)
Calcium; Magnesium; Zinc	1	(0.1)	1	(0.1)	2	(0.1)
Boron; Calcium Carbonate; Calcium Citrate; Calcium Citrate Malate; Colecalciferol; Copper Gluconate; Magnesium Citrate; Magnesium Gluconate; Magnesium Oxide; Manganese Gluconate; Phytomenadione; Sodium; Zinc Gluc	1	(0.1)	0		1	(0.0)
Calcitriol; Calcium Carbonate; Zinc	0		1	(0.1)	1	(0.0)
Calcium Carbonate; Colecalciferol; Magnesium	1	(0.1)	0		1	(0.0)
Calcium Citrate; Colecalciferol	0		1	(0.1)	1	(0.0)
Calcium Phosphate; Colecalciferol	0		1	(0.1)	1	(0.0)
Calcium, Combinations With Vitamin D And/Or Other Drugs	0		1	(0.1)	1	(0.0)
Calcium; Colecalciferol; Magnesium	1	(0.1)	0		1	(0.0)
Combinations Of Various Lipid Modifying Agents, C10ba	9	(0.4)	23	(1.1)	32	(0.7)
Ezetimibe; Rosuvastatin Calcium	4	(0.2)	7	(0.3)	11	(0.2)
Atorvastatin Calcium; Ezetimibe	3	(0.1)	4	(0.2)	7	(0.2)
Fenofibrate; Pravastatin Sodium	2	(0.1)	3	(0.1)	5	(0.1)
Ezetimibe; Simvastatin	0		4	(0.2)	4	(0.1)
Atorvastatin Calcium; Fenofibrate	0		2	(0.1)	2	(0.1)
Fenofibrate; Rosuvastatin Calcium	0		2	(0.1)	2	(0.1)
Atorvastatin; Fenofibrate	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Benzothiazepine Derivatives, C08db	18	(0.8)	12	(0.6)	30	(0.7)
Diltiazem	13	(0.6)	7	(0.3)	20	(0.5)
Diltiazem Hydrochloride	5	(0.2)	5	(0.2)	10	(0.2)
Opioids In Combination With Non-Opioid Analgesics, N02aj	16	(0.7)	14	(0.7)	30	(0.7)
Hydrocodone Bitartrate; Paracetamol	5	(0.2)	5	(0.2)	10	(0.2)
Codeine Phosphate; Paracetamol	5	(0.2)	2	(0.1)	7	(0.2)
Oxycodone Hydrochloride; Paracetamol	1	(0.1)	4	(0.2)	5	(0.1)
Paracetamol; Tramadol Hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Caffeine; Codeine; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Hydrocodone; Paracetamol	2	(0.1)	0		2	(0.1)
Dexketoprofen Trometamol; Tramadol Hydrochloride	0		1	(0.1)	1	(0.0)
Other Opioids, N02ax	17	(0.8)	13	(0.6)	30	(0.7)
Tramadol	14	(0.7)	10	(0.5)	24	(0.6)
Tramadol Hydrochloride	3	(0.1)	3	(0.1)	6	(0.1)
Other Plain Vitamin Preparations, A11ha	16	(0.7)	14	(0.7)	30	(0.7)
Biotin	16	(0.7)	13	(0.6)	29	(0.7)
Adenine Hydrochloride	0		1	(0.1)	1	(0.0)
Benzodiazepine Derivatives, N03ae	16	(0.7)	13	(0.6)	29	(0.7)
Clonazepam	16	(0.7)	13	(0.6)	29	(0.7)
Bile Acids And Derivatives, A05aa	15	(0.7)	12	(0.6)	27	(0.6)
Ursodeoxycholic Acid	15	(0.7)	12	(0.6)	27	(0.6)
Centrally Acting Sympathomimetics, N06ba	8	(0.4)	19	(0.9)	27	(0.6)
Amfetamine Aspartate; Amfetamine Sulfate; Dexamfetamine Saccharate; Dexamfetamine Sulfate	2	(0.1)	6	(0.3)	8	(0.2)
Dexamfetamine	1	(0.1)	3	(0.1)	4	(0.1)
Modafinil	3	(0.1)	1	(0.1)	4	(0.1)
Lisdexamfetamine Mesilate	0		3	(0.1)	3	(0.1)
Armodafinil	1	(0.1)	1	(0.1)	2	(0.1)
Methylphenidate	1	(0.1)	1	(0.1)	2	(0.1)
Methylphenidate Hydrochloride	0		2	(0.1)	2	(0.1)
Atomoxetine	1	(0.1)	0		1	(0.0)
Atomoxetine Hydrochloride	1	(0.1)	0		1	(0.0)
Dexamfetamine Sulfate	0		1	(0.1)	1	(0.0)
Dexmethylphenidate Hydrochloride	0		1	(0.1)	1	(0.0)
Melatonin Receptor Agonists, N05ch	14	(0.7)	12	(0.6)	26	(0.6)
Melatonin	13	(0.6)	12	(0.6)	25	(0.6)
Magnesium; Melatonin	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Multivitamins With Minerals, A11aa	13	(0.6)	13	(0.6)	26	(0.6)
Ascorbic Acid; Calcium; Minerals Nos; Retinol; Tocopheryl Acetate; Vitamin B Nos; Vitamins Nos; Zinc	8	(0.4)	7	(0.3)	15	(0.3)
Multivitamins With Minerals [Umbrella Term]	0		4	(0.2)	4	(0.1)
Ascorbic Acid; Betacarotene; Biotin; Calcium; Chlorine; Chromium; Copper; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Folic Acid; Iodine; Magnesium; Manganese; Molybdenum; Nickel; Nicotinamide; Pantothenic Acid; Phos	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Betacarotene; Biotin; Calcium; Chromium; Copper; Folic Acid; Iodine; Iron; Magnesium; Manganese; Molybdenum; Nicotinic Acid; Pantothenic Acid; Phosphorus; Pyridoxine Hydrochloride; Retinol; Riboflavin; S	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Betacarotene; Biotin; Calcium Carbonate; Calcium Pantothenate; Calcium Phosphate; Calcium Phosphate Dibasic; Chromic Chloride; Cupric Oxide; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ergocalcif	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Betacarotene; Biotin; Calcium Carbonate; Calcium Pantothenate; Chromic Chloride; Colecalciferol; Cupric Oxide; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Folic Acid; Magnesium O	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Biotin; Calcium; Calcium Pantothenate; Chloride; Chromium; Colecalciferol; Copper; Folic Acid; Iodine; Iron; Magnesium; Manganese; Molybdenum; Nickel; Nicotinamide; Phosphorus; Potassium; Pyridoxine Hydr	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate; Colecalciferol; Copper Sulfate; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Folic Acid; Manganese Sulfate; Nicotinamide; Potassium Iodid	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Calcium Phosphate Dibasic; Cupric Oxide; Tocopheryl Acetate; Xantofyl; Zinc Oxide	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Unspecified Herbal And Traditional Medicine, V90	11	(0.5)	15	(0.7)	26	(0.6)
Malus Spp. Vinegar Extract	5	(0.2)	1	(0.1)	6	(0.1)
Unspecified Herbal	2	(0.1)	3	(0.1)	5	(0.1)
Traditional Medicine	1	(0.1)	3	(0.1)	4	(0.1)
Herbal Preparation	2	(0.1)	0		2	(0.1)
Alisma Orientale Tube; Anemarrhena Asphodeloides Rhizome; Cornus Officinalis Fruit; Dioscorea Polystachya Rhizome; Paeonia X Suffruticosa Root Bark; Phellodendron Amurense Bark; Poria Cocos Sclerotium; Rehma	0		1	(0.1)	1	(0.0)
Allium Sativum Bulb; Borneol; Crataegus Pinnatifida Fruit; Erigeron Breviscapus Herb; Ginkgo Biloba Leaf; Gynostemma Pentaphyllum Whole Plant; Panax Notoginseng Root; Salvia Miltiorrhiza Root	0		1	(0.1)	1	(0.0)
Astragalus Mongholicus Root; Cyathula Officinalis Root; Epimedium Brevicornu Herb; Plantago Asiatica Herb; Typha Angustifolia Pollen	0		1	(0.1)	1	(0.0)
Bacopa Monnieri Herb; Camellia Sinensis Leaf; Curcuma Longa Rhizome; Silybum Marianum Seed; Withania Somnifera Root	0		1	(0.1)	1	(0.0)
Cinnamomum Spp.	0		1	(0.1)	1	(0.0)
Ginseng Nos	0		1	(0.1)	1	(0.0)
Herbal Extract Nos	0		1	(0.1)	1	(0.0)
Pueraria Montana	0		1	(0.1)	1	(0.0)
Quercus Salicina Extract	0		1	(0.1)	1	(0.0)
Rubus Idaeus Leaf; Sambucus Nigra Flower; Sambucus Nigra Fruit	1	(0.1)	0		1	(0.0)
Traditional Chinese Medicine (Tcm) Decoction	1	(0.1)	0		1	(0.0)
Anticholinergics, R03bb	18	(0.8)	7	(0.3)	25	(0.6)
Ipratropium Bromide	8	(0.4)	0		8	(0.2)
Tiotropium Bromide Monohydrate	4	(0.2)	3	(0.1)	7	(0.2)
Ipratropium	2	(0.1)	2	(0.1)	4	(0.1)
Tiotropium Bromide	2	(0.1)	1	(0.1)	3	(0.1)
Umeclidinium	2	(0.1)	0		2	(0.1)
Umeclidinium Bromide	1	(0.1)	1	(0.1)	2	(0.1)
Aclidinium Bromide	0		1	(0.1)	1	(0.0)
Antidiarrheal Microorganisms, A07fa	11	(0.5)	14	(0.7)	25	(0.6)
Bifidobacterium Lactis	8	(0.4)	6	(0.3)	14	(0.3)
Bacillus Mesentericus; Clostridium Butyricum; Enterococcus Faecalis	1	(0.1)	2	(0.1)	3	(0.1)
Bacillus Clausii; Bacillus Coagulans; Bacillus Indicus; Bacillus Lichenformis; Bacillus Subtilis	0		1	(0.1)	1	(0.0)
Bacillus Subtilis; Enterococcus Faecalis; Lactobacillus Acidophilus	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum; Bifidobacterium Infantis	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum; Bifidobacterium Lactis; Lactobacillus Acidophilus	1	(0.1)	0		1	(0.0)
Bifidobacterium Longum; Enterococcus Faecalis; Lactobacillus Acidophilus	0		1	(0.1)	1	(0.0)
Bifidobacterium Nos	0		1	(0.1)	1	(0.0)
Saccharomyces Boulardii	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Benzodiazepine Derivatives, N05cd	14	(0.7)	11	(0.5)	25	(0.6)
Temazepam	5	(0.2)	3	(0.1)	8	(0.2)
Brotizolam	4	(0.2)	2	(0.1)	6	(0.1)
Flunitrazepam	1	(0.1)	2	(0.1)	3	(0.1)
Triazolam	1	(0.1)	2	(0.1)	3	(0.1)
Estazolam	1	(0.1)	1	(0.1)	2	(0.1)
Loprazolam Mesilate	1	(0.1)	0		1	(0.0)
Lormetazepam	0		1	(0.1)	1	(0.0)
Midazolam	1	(0.1)	0		1	(0.0)
Nitrazepam	1	(0.1)	0		1	(0.0)
Rilmazafone Hydrochloride	0		1	(0.1)	1	(0.0)
Diazepines, Oxazepines, Thiazepines And Oxepines, N05ah	14	(0.7)	11	(0.5)	25	(0.6)
Quetiapine Fumarate	10	(0.5)	3	(0.1)	13	(0.3)
Olanzapine	2	(0.1)	4	(0.2)	6	(0.1)
Quetiapine	2	(0.1)	4	(0.2)	6	(0.1)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12, A11db	14	(0.7)	11	(0.5)	25	(0.6)
Benfotiamine; Cyanocobalamin; Pyridoxine Hydrochloride	6	(0.3)	3	(0.1)	9	(0.2)
Cyanocobalamin; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	3	(0.1)	3	(0.1)	6	(0.1)
Benfotiamine; Cyanocobalamin; Pyridoxine	2	(0.1)	3	(0.1)	5	(0.1)
Pyridoxine Hydrochloride; Thiamine Mononitrate	0		2	(0.1)	2	(0.1)
Benfotiamine; Cyanocobalamin	1	(0.1)	0		1	(0.0)
Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Vitamin B1 Nos; Vitamin B12 Nos	1	(0.1)	0		1	(0.0)
Natural Opium Alkaloids, N02aa	8	(0.4)	16	(0.7)	24	(0.6)
Oxycodone	2	(0.1)	7	(0.3)	9	(0.2)
Hydrocodone	4	(0.2)	4	(0.2)	8	(0.2)
Oxycodone Hydrochloride	1	(0.1)	3	(0.1)	4	(0.1)
Morphine Sulfate	0		3	(0.1)	3	(0.1)
Hydromorphone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02bx	9	(0.4)	14	(0.7)	23	(0.5)
Rebamipide	5	(0.2)	10	(0.5)	15	(0.3)
Bismuth Subsalicylate	2	(0.1)	0		2	(0.1)
Irsogladine Maleate	1	(0.1)	1	(0.1)	2	(0.1)
Benexate Hcl Beta-Cyclodextrin Clathrate	0		1	(0.1)	1	(0.0)
Bismuth Oxide; Bismuth Subgallate; Zinc Oxide	0		1	(0.1)	1	(0.0)
Calcium Carbonate; Magnesium Carbonate; Sodium Alginate	1	(0.1)	0		1	(0.0)
Ecabet Monosodium	0		1	(0.1)	1	(0.0)
Other Viral Vaccines, J07bx	12	(0.6)	11	(0.5)	23	(0.5)
Tozinameran	9	(0.4)	5	(0.2)	14	(0.3)
Elasomeran	2	(0.1)	3	(0.1)	5	(0.1)
Covid-19 Vaccine Nrvv Ad (Chadox1 Ncov-19)	1	(0.1)	2	(0.1)	3	(0.1)
Covid-19 Vaccine	0		1	(0.1)	1	(0.0)
Bisphosphonates, M05ba	13	(0.6)	9	(0.4)	22	(0.5)
Alendronate Sodium	6	(0.3)	5	(0.2)	11	(0.2)
Minodronic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Alendronic Acid	2	(0.1)	0		2	(0.1)
Ibandronate Sodium	2	(0.1)	0		2	(0.1)
Risedronate Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Clodronate Disodium	0		1	(0.1)	1	(0.0)
Risedronic Acid	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ace Inhibitors And Calcium Channel Blockers, C09bb	11	(0.5)	10	(0.5)	21	(0.5)
Amlodipine Besilate; Perindopril Arginine	4	(0.2)	1	(0.1)	5	(0.1)
Amlodipine Besilate; Ramipril	1	(0.1)	3	(0.1)	4	(0.1)
Amlodipine Besilate; Benazepril Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Amlodipine Besilate; Lisinopril	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Perindopril Erbumine	1	(0.1)	1	(0.1)	2	(0.1)
Enalapril Maleate; Lercanidipine Hydrochloride	2	(0.1)	0		2	(0.1)
Amlodipine Besilate; Perindopril Tosilate	0		1	(0.1)	1	(0.0)
Amlodipine; Benazepril	0		1	(0.1)	1	(0.0)
Trandolapril; Verapamil Hydrochloride	1	(0.1)	0		1	(0.0)
Other Immunosuppressants, L04ax	13	(0.6)	7	(0.3)	20	(0.5)
Methotrexate	10	(0.5)	5	(0.2)	15	(0.3)
Azathioprine	1	(0.1)	2	(0.1)	3	(0.1)
Methotrexate Sodium	2	(0.1)	0		2	(0.1)
Other Antipsychotics, N05ax	7	(0.3)	12	(0.6)	19	(0.4)
Aripiprazole	5	(0.2)	8	(0.4)	13	(0.3)
Risperidone	2	(0.1)	4	(0.2)	6	(0.1)
Aminoalkyl Ethers, R06aa	12	(0.6)	6	(0.3)	18	(0.4)
Diphenhydramine Hydrochloride	8	(0.4)	3	(0.1)	11	(0.2)
Diphenhydramine	4	(0.2)	0		4	(0.1)
Diphenhydramine Hydrochloride; Paracetamol	0		3	(0.1)	3	(0.1)
Carbonic Anhydrase Inhibitors, S01ec	9	(0.4)	9	(0.4)	18	(0.4)
Brinzolamide	5	(0.2)	3	(0.1)	8	(0.2)
Dorzolamide	2	(0.1)	5	(0.2)	7	(0.2)
Dorzolamide Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Brimonidine Tartrate; Brinzolamide	1	(0.1)	0		1	(0.0)
Contact Laxatives, A06ab	5	(0.2)	13	(0.6)	18	(0.4)
Sennoside A+B	2	(0.1)	5	(0.2)	7	(0.2)
Sennoside A+B Calcium	2	(0.1)	5	(0.2)	7	(0.2)
Sodium Picosulfate	0		3	(0.1)	3	(0.1)
Docusate Sodium; Senna Alexandrina	1	(0.1)	0		1	(0.0)
Digitalis Glycosides, C01aa	10	(0.5)	8	(0.4)	18	(0.4)
Digoxin	10	(0.5)	5	(0.2)	15	(0.3)
Metildigoxin	0		2	(0.1)	2	(0.1)
Digitoxin	0		1	(0.1)	1	(0.0)
Dopamine Agonists, N04bc	10	(0.5)	8	(0.4)	18	(0.4)
Pramipexole	4	(0.2)	3	(0.1)	7	(0.2)
Ropinirole	2	(0.1)	3	(0.1)	5	(0.1)
Pramipexole Dihydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Pramipexole Dihydrochloride Monohydrate	1	(0.1)	0		1	(0.0)
Ropinirole Hydrochloride	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Multivitamins, Other Combinations, A11ab	9	(0.4)	9	(0.4)	18	(0.4)
Ascorbic Acid; Ergocalciferol; Folic Acid; Nicotinamide; Panthenol; Retinol; Riboflavin; Thiamine Hydrochloride	5	(0.2)	7	(0.3)	12	(0.3)
Ascorbic Acid; Betacarotene; Bioflavonoids Nos; Biotin; Calcium Citrate; Calcium Pantothenate; Choline Bitartrate; Chromium Picolinate; Colecalciferol; Copper Gluconate; Cyanocobalamin; Dl-Alpha Tocopheryl Aceta	1	(0.1)	1	(0.1)	2	(0.1)
Multivitamins, Other Combinations	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Betacarotene; Biotin; Boron; Calcium; Calcium Pantothenate; Chloride; Chromium; Colecalciferol; Copper; Cyanocobalamin; Folic Acid; Iodine; Iron; Lycopene; Magnesium; Manganese; Molybdenum; Nickel; Nicoti	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium; Colecalciferol; Copper; Ferrous Fumarate; Folic Acid; Iodine; Magnesium; Manganese; Nicotinamide; Panax Ginseng Root; Pantothenic Acid; Phosphorus; Potassium; Pyridoxine Hydrochloride; Retino	1	(0.1)	0		1	(0.0)
Antiarrhythmics, Class Iii, C01bd	11	(0.5)	6	(0.3)	17	(0.4)
Amiodarone Hydrochloride	5	(0.2)	3	(0.1)	8	(0.2)
Amiodarone	5	(0.2)	1	(0.1)	6	(0.1)
Dofetilide	1	(0.1)	1	(0.1)	2	(0.1)
Dronedarone	0		1	(0.1)	1	(0.0)
Bioflavonoids, C05ca	9	(0.4)	8	(0.4)	17	(0.4)
Diosmin	5	(0.2)	5	(0.2)	10	(0.2)
Diosmin; Hesperidin	4	(0.2)	2	(0.1)	6	(0.1)
Ascorbic Acid; Rutoside	0		1	(0.1)	1	(0.0)
Nicotinic Acid And Derivatives, C10ad	11	(0.5)	6	(0.3)	17	(0.4)
Nicotinic Acid	8	(0.4)	4	(0.2)	12	(0.3)
Tocopheryl Nicotinate	3	(0.1)	1	(0.1)	4	(0.1)
Acipimox	0		1	(0.1)	1	(0.0)
Purine Derivatives, C04ad	12	(0.6)	5	(0.2)	17	(0.4)
Pentoxifylline	12	(0.6)	5	(0.2)	17	(0.4)
Aminosalicylic Acid And Similar Agents, A07ec	2	(0.1)	13	(0.6)	15	(0.3)
Mesalazine	2	(0.1)	13	(0.6)	15	(0.3)
Azaspirodecanedione Derivatives, N05be	6	(0.3)	9	(0.4)	15	(0.3)
Buspirone Hydrochloride	5	(0.2)	3	(0.1)	8	(0.2)
Buspirone	1	(0.1)	6	(0.3)	7	(0.2)
Glycogenolytic Hormones, H04aa	7	(0.3)	8	(0.4)	15	(0.3)
Glucagon	5	(0.2)	8	(0.4)	13	(0.3)
Glucagon Hydrochloride	2	(0.1)	0		2	(0.1)
Other Antiepileptics, N03ax	8	(0.4)	7	(0.3)	15	(0.3)
Topiramate	4	(0.2)	7	(0.3)	11	(0.2)
Levetiracetam	4	(0.2)	0		4	(0.1)
Selective Serotonin (5ht1) Agonists, N02cc	8	(0.4)	7	(0.3)	15	(0.3)
Sumatriptan	6	(0.3)	4	(0.2)	10	(0.2)
Rizatriptan Benzoate	0		2	(0.1)	2	(0.1)
Eletriptan Hydrobromide	1	(0.1)	0		1	(0.0)
Rizatriptan	0		1	(0.1)	1	(0.0)
Sumatriptan Succinate	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. 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): NA; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y")
adcm.xpt; variable(s): TRAG1 CMDECOD CMCLAS CMCLASCD; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y") & (SCSTT == "ONGOING AT")

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Antiarrhythmics, Class Ic, C01bc	7	(0.3)	7	(0.3)	14	(0.3)
Propafenone Hydrochloride	2	(0.1)	4	(0.2)	6	(0.1)
Flecainide Acetate	3	(0.1)	1	(0.1)	4	(0.1)
Flecainide	1	(0.1)	1	(0.1)	2	(0.1)
Propafenone	1	(0.1)	1	(0.1)	2	(0.1)
Antivertigo Preparations, N07ca	7	(0.3)	7	(0.3)	14	(0.3)
Betahistine Hydrochloride	2	(0.1)	4	(0.2)	6	(0.1)
Betahistine	2	(0.1)	3	(0.1)	5	(0.1)
Acetylleucine	1	(0.1)	0		1	(0.0)
Betahistine Mesilate	1	(0.1)	0		1	(0.0)
Cinnarizine	1	(0.1)	0		1	(0.0)
Other Psychostimulants And Nootropics, N06bx	7	(0.3)	7	(0.3)	14	(0.3)
Piracetam	4	(0.2)	3	(0.1)	7	(0.2)
Vinpocetine	3	(0.1)	4	(0.2)	7	(0.2)
Sympathomimetics, R01ba	4	(0.2)	10	(0.5)	14	(0.3)
Pseudoephedrine	1	(0.1)	2	(0.1)	3	(0.1)
Pseudoephedrine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Cetirizine Hydrochloride; Pseudoephedrine Hydrochloride	0		2	(0.1)	2	(0.1)
Loratadine; Pseudoephedrine Sulfate	1	(0.1)	1	(0.1)	2	(0.1)
Atropa Belladonna Total Alkaloid Extract; Caffeine; Chlorphenamine Maleate; Dipotassium Glycyrrhizate; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Ebastine; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Naproxen Sodium; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Pseudoephedrine Sulfate	0		1	(0.1)	1	(0.0)
Vitamin B1, Plain, A11da	9	(0.4)	5	(0.2)	14	(0.3)
Thiamine Hydrochloride	4	(0.2)	3	(0.1)	7	(0.2)
Benfotiamine	3	(0.1)	1	(0.1)	4	(0.1)
Fursultiamine	0		1	(0.1)	1	(0.0)
Fursultiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Thiamine	1	(0.1)	0		1	(0.0)
Vitamins, Other Combinations, A11jc	5	(0.2)	9	(0.4)	14	(0.3)
Colecalciferol; Folic Acid; Mecobalamin; Pyridoxine Hydrochloride; Thioctic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Vitamins, Other Combinations	0		3	(0.1)	3	(0.1)
Ascorbic Acid; Betacarotene; Calcium Carbonate; Calcium Pantothenate; Calcium Silicate; Cellulose Microcrystalline; Colecalciferol; Croscarmellose Sodium; Cyanocobalamin; Dextrin; Dl-Alpha Tocopheryl Acetate; Fe	0		2	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate Dibasic; Colecalciferol; Copper Sulfate; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Magnesium Oxide; Manganese Sulfate; Nicotinamide; Po	1	(0.1)	1	(0.1)	2	(0.1)
Biotin; Calcium Carbonate; Gelatine Hydrolysate	1	(0.1)	0		1	(0.0)
Minerals Nos; Omega-3 Fatty Acids; Vitamins Nos	1	(0.1)	0		1	(0.0)
Pyridoxine Hydrochloride; Thioctic Acid; Vitamin B1 Nos; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Selenium; Thioctic Acid; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Coxibs, M01ah	4	(0.2)	9	(0.4)	13	(0.3)
Celecoxib	4	(0.2)	8	(0.4)	12	(0.3)
Etoricoxib	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Diphenylmethane Derivatives, N05bb	9	(0.4)	4	(0.2)	13	(0.3)
Hydroxyzine	8	(0.4)	3	(0.1)	11	(0.2)
Hydroxyzine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Other Drugs For Constipation, A06ax	5	(0.2)	8	(0.4)	13	(0.3)
Linaclotide	2	(0.1)	3	(0.1)	5	(0.1)
Lubiprostone	0		4	(0.2)	4	(0.1)
Elobixibat	1	(0.1)	0		1	(0.0)
Potassium Bitartrate; Sodium Bicarbonate	1	(0.1)	0		1	(0.0)
Prucalopride	0		1	(0.1)	1	(0.0)
Tegaserod Maleate	1	(0.1)	0		1	(0.0)
Other Potassium-Sparing Agents, C03db	8	(0.4)	5	(0.2)	13	(0.3)
Triamterene	5	(0.2)	3	(0.1)	8	(0.2)
Amiloride	3	(0.1)	1	(0.1)	4	(0.1)
Amiloride Hydrochloride	0		1	(0.1)	1	(0.0)
Phenylalkylamine Derivatives, C08da	3	(0.1)	10	(0.5)	13	(0.3)
Verapamil	2	(0.1)	5	(0.2)	7	(0.2)
Verapamil Hydrochloride	1	(0.1)	5	(0.2)	6	(0.1)
Propulsives, A03fa	4	(0.2)	9	(0.4)	13	(0.3)
Domperidone	3	(0.1)	7	(0.3)	10	(0.2)
Cinitapride	0		1	(0.1)	1	(0.0)
Itopride Hydrochloride	1	(0.1)	0		1	(0.0)
Mosapride Citrate	0		1	(0.1)	1	(0.0)
Enzymes, C04af	8	(0.4)	4	(0.2)	12	(0.3)
Kallidinogenase	8	(0.4)	4	(0.2)	12	(0.3)
Other Vasodilators Used In Cardiac Diseases, C01dx	5	(0.2)	7	(0.3)	12	(0.3)
Nicorandil	3	(0.1)	4	(0.2)	7	(0.2)
Sacubitril	1	(0.1)	2	(0.1)	3	(0.1)
Molsidomine	1	(0.1)	1	(0.1)	2	(0.1)
Serotonin (5ht3) Antagonists, A04aa	4	(0.2)	8	(0.4)	12	(0.3)
Ondansetron	3	(0.1)	7	(0.3)	10	(0.2)
Ondansetron Hydrochloride	1	(0.1)	0		1	(0.0)
Ramosetron Hydrochloride	0		1	(0.1)	1	(0.0)
Tumor Necrosis Factor Alpha (Tnf-) Inhibitors, L04ab	7	(0.3)	5	(0.2)	12	(0.3)
Adalimumab	5	(0.2)	2	(0.1)	7	(0.2)
Etanercept	0		2	(0.1)	2	(0.1)
Certolizumab Pegol	1	(0.1)	0		1	(0.0)
Golimumab	0		1	(0.1)	1	(0.0)
Infliximab	1	(0.1)	0		1	(0.0)
Ace Inhibitors, Other Combinations, C09bx	7	(0.3)	4	(0.2)	11	(0.2)
Amlodipine Besilate; Indapamide; Perindopril Arginine	7	(0.3)	1	(0.1)	8	(0.2)
Amlodipine Besilate; Indapamide; Perindopril Erbumine	0		2	(0.1)	2	(0.1)
Metoprolol Tartrate; Ramipril	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids, R03al	6	(0.3)	5	(0.2)	11	(0.2)
Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate	1	(0.1)	3	(0.1)	4	(0.1)
Olodaterol Hydrochloride; Tiotropium Bromide Monohydrate	3	(0.1)	0		3	(0.1)
Glycopyrronium Bromide; Indacaterol Maleate	2	(0.1)	0		2	(0.1)
Ipratropium Bromide; Levosalbutamol Sulfate	0		1	(0.1)	1	(0.0)
Umeclidinium Bromide; Vilanterol Trifenatate	0		1	(0.1)	1	(0.0)
Direct Thrombin Inhibitors, B01ae	6	(0.3)	5	(0.2)	11	(0.2)
Dabigatran Etexilate Mesilate	5	(0.2)	3	(0.1)	8	(0.2)
Dabigatran	1	(0.1)	1	(0.1)	2	(0.1)
Dabigatran Etexilate	0		1	(0.1)	1	(0.0)
Enzyme Preparations, A09aa	6	(0.3)	5	(0.2)	11	(0.2)
Pancreatin	3	(0.1)	4	(0.2)	7	(0.2)
Pancrelipase	1	(0.1)	1	(0.1)	2	(0.1)
Duodenum Siccum; Pancreatin	1	(0.1)	0		1	(0.0)
Pancreas Powder	1	(0.1)	0		1	(0.0)
Lipid Modifying Agents In Combination With Other Drugs, C10bx	5	(0.2)	6	(0.3)	11	(0.2)
Olmesartan Medoxomil; Rosuvastatin Calcium	1	(0.1)	2	(0.1)	3	(0.1)
Acetylsalicylic Acid; Atorvastatin Calcium	1	(0.1)	1	(0.1)	2	(0.1)
Acetylsalicylic Acid; Atorvastatin	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Rosuvastatin Calcium	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Atorvastatin Calcium; Perindopril Arginine	0		1	(0.1)	1	(0.0)
Amlodipine Besilate; Rosuvastatin Calcium; Telmisartan	0		1	(0.1)	1	(0.0)
Candesartan Cilexetil; Rosuvastatin Calcium	1	(0.1)	0		1	(0.0)
Fish Oil; Ubidecarenone	0		1	(0.1)	1	(0.0)
Osmotically Acting Laxatives, A06ad	7	(0.3)	4	(0.2)	11	(0.2)
Macrogol 3350	6	(0.3)	2	(0.1)	8	(0.2)
Benzoic Acid; Lactitol	0		1	(0.1)	1	(0.0)
Lactulose	1	(0.1)	0		1	(0.0)
Macrogol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Selective Immunosuppressants, L04aa	5	(0.2)	6	(0.3)	11	(0.2)
Mycophenolate Mofetil	2	(0.1)	3	(0.1)	5	(0.1)
Leflunomide	1	(0.1)	2	(0.1)	3	(0.1)
Iguratimod	1	(0.1)	0		1	(0.0)
Mycophenolate Sodium	1	(0.1)	0		1	(0.0)
Vedolizumab	0		1	(0.1)	1	(0.0)
Carboxamide Derivatives, N03af01	4	(0.2)	6	(0.3)	10	(0.2)
Carbamazepine	4	(0.2)	6	(0.3)	10	(0.2)
Heparin Group, B01ab	6	(0.3)	4	(0.2)	10	(0.2)
Sulodexide	4	(0.2)	2	(0.1)	6	(0.1)
Heparin	1	(0.1)	1	(0.1)	2	(0.1)
Enoxaparin Sodium	1	(0.1)	0		1	(0.0)
Tinzaparin Sodium	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Imidazole And Triazole Derivatives, D01ac	7	(0.3)	3	(0.1)	10	(0.2)
Luliconazole	3	(0.1)	1	(0.1)	4	(0.1)
Efinaconazole	1	(0.1)	2	(0.1)	3	(0.1)
Betamethasone Dipropionate; Clotrimazole	1	(0.1)	0		1	(0.0)
Betamethasone; Clotrimazole	1	(0.1)	0		1	(0.0)
Hydrocortisone; Miconazole Nitrate	1	(0.1)	0		1	(0.0)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors, J05ab	6	(0.3)	4	(0.2)	10	(0.2)
Valaciclovir Hydrochloride	6	(0.3)	4	(0.2)	10	(0.2)
Other Antipsoriatics For Topical Use, D05ax	8	(0.4)	2	(0.1)	10	(0.2)
Calcipotriol	4	(0.2)	0		4	(0.1)
Betamethasone Dipropionate; Calcipotriol	1	(0.1)	1	(0.1)	2	(0.1)
Betamethasone Dipropionate; Calcipotriol Monohydrate	1	(0.1)	1	(0.1)	2	(0.1)
Betamethasone; Calcipotriol	1	(0.1)	0		1	(0.0)
Calcipotriol Monohydrate	1	(0.1)	0		1	(0.0)
Sulfur-Containing Imidazole Derivatives, H03bb	6	(0.3)	4	(0.2)	10	(0.2)
Thiamazole	5	(0.2)	4	(0.2)	9	(0.2)
Carbimazole	1	(0.1)	0		1	(0.0)
Synthetic Anticholinergics, Esters With Tertiary Amino Group, A03aa	5	(0.2)	5	(0.2)	10	(0.2)
Dicycloverine	2	(0.1)	4	(0.2)	6	(0.1)
Mebeverine Hydrochloride	2	(0.1)	0		2	(0.1)
Dicycloverine Hydrochloride	0		1	(0.1)	1	(0.0)
Trimebutine Maleate	1	(0.1)	0		1	(0.0)
Antipropulsives, A07da	5	(0.2)	4	(0.2)	9	(0.2)
Loperamide Hydrochloride	4	(0.2)	2	(0.1)	6	(0.1)
Loperamide	0		2	(0.1)	2	(0.1)
Atropine Sulfate; Diphenoxylate Hydrochloride	1	(0.1)	0		1	(0.0)
Eluxadoline	1	(0.1)	0		1	(0.0)
Hydrazinophthalazine Derivatives, C02db	3	(0.1)	6	(0.3)	9	(0.2)
Hydralazine	1	(0.1)	6	(0.3)	7	(0.2)
Dihydralazine Sulfate	1	(0.1)	0		1	(0.0)
Hydralazine Hydrochloride	1	(0.1)	0		1	(0.0)
Preparations With No Effect On Uric Acid Metabolism, M04ac	4	(0.2)	5	(0.2)	9	(0.2)
Colchicine	4	(0.2)	5	(0.2)	9	(0.2)
Progestogens And Estrogens, Fixed Combinations, G03aa	4	(0.2)	5	(0.2)	9	(0.2)
Ethinylestradiol; Norgestimate	2	(0.1)	1	(0.1)	3	(0.1)
Drospirenone; Ethinylestradiol Betadex Clathrate	1	(0.1)	1	(0.1)	2	(0.1)
Ethinylestradiol; Gestodene	1	(0.1)	1	(0.1)	2	(0.1)
Drospirenone; Ethinylestradiol	0		1	(0.1)	1	(0.0)
Ethinylestradiol; Norelgestromin	0		1	(0.1)	1	(0.0)
Aldose Reductase Inhibitors, A10xa	6	(0.3)	2	(0.1)	8	(0.2)
Epalrestat	6	(0.3)	2	(0.1)	8	(0.2)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations, C09dx	4	(0.2)	4	(0.2)	8	(0.2)
Amlodipine Besilate; Hydrochlorothiazide; Olmesartan Medoxomil	3	(0.1)	1	(0.1)	4	(0.1)
Amlodipine Besilate; Hydrochlorothiazide; Valsartan	0		2	(0.1)	2	(0.1)
Sacubitril; Valsartan	1	(0.1)	1	(0.1)	2	(0.1)
Carbamic Acid Esters, M03ba	3	(0.1)	5	(0.2)	8	(0.2)
Methocarbamol	3	(0.1)	5	(0.2)	8	(0.2)
Iron In Combination With Folic Acid, B03ad	3	(0.1)	5	(0.2)	8	(0.2)
Ferrous Sulfate; Folic Acid	3	(0.1)	1	(0.1)	4	(0.1)
Ferrous Ascorbate; Folic Acid	0		2	(0.1)	2	(0.1)
Ferric Hydroxide Polymaltose Complex; Folic Acid	0		1	(0.1)	1	(0.0)
Ferrous Bisglycinate; Folic Acid	0		1	(0.1)	1	(0.0)
Low-Ceiling Diuretics And Potassium-Sparing Agents, C03ea	7	(0.3)	1	(0.1)	8	(0.2)
Hydrochlorothiazide; Triamterene	3	(0.1)	1	(0.1)	4	(0.1)
Amiloride Hydrochloride; Hydrochlorothiazide	3	(0.1)	0		3	(0.1)
Amiloride; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Opium Alkaloids And Derivatives, R05da	4	(0.2)	4	(0.2)	8	(0.2)
Codeine	3	(0.1)	2	(0.1)	5	(0.1)
Chlorphenamine Maleate; Dihydrocodeine Phosphate; Methylephedrine Hydrochloride-Dl	0		1	(0.1)	1	(0.0)
Codeine Phosphate	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide	0		1	(0.1)	1	(0.0)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids, M01ax	4	(0.2)	4	(0.2)	8	(0.2)
Nabumetone	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Chondroitin Sulfate; Glucosamine Sulfate; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Calcium; Glucosamine	0		1	(0.1)	1	(0.0)
Chondroitin Sulfate; Glucosamine Hydrochloride; Hyaluronic Acid; Maltodextrin; Scutellaria Baicalensis Root; Senegalia Catechu Bark	0		1	(0.1)	1	(0.0)
Glucosamine Sulfate Potassium Chloride	0		1	(0.1)	1	(0.0)
Glucosamine Sulfate; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	1	(0.1)	0		1	(0.0)
Tetracyclines, J01aa	4	(0.2)	4	(0.2)	8	(0.2)
Doxycycline	2	(0.1)	3	(0.1)	5	(0.1)
Doxycycline Hyclate	1	(0.1)	1	(0.1)	2	(0.1)
Doxycycline Monohydrate	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamins With Minerals, A11jb	4	(0.2)	4	(0.2)	8	(0.2)
Vitamins With Minerals	2	(0.1)	3	(0.1)	5	(0.1)
Biotin; Calcium Pantothenate; Centella Asiatica; Choline Bitartrate; Cyanocobalamin; Folic Acid; Inositol; Medicago Sativa; Nicotinamide; Panax Ginseng; Pyridoxine Hydrochloride; Riboflavin; Rosa Canina; Thiamine	1	(0.1)	0		1	(0.0)
Biotin; Calcium Pantothenate; Chromic Chloride; Colecalciferol; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Folic Acid; Manganese Sulfate; Nicotinamide; Phytomenadione; Potassium Iodide; Pyridoxine Hydrochlorid	1	(0.1)	0		1	(0.0)
Chromium Picolinate; Cyanocobalamin; Folic Acid; Nicotinamide; Pyridoxine Hydrochloride; Selenious Acid; Zinc Sulfate Monohydrate	0		1	(0.1)	1	(0.0)
Antineovascularisation Agents, S01la	4	(0.2)	3	(0.1)	7	(0.2)
Aflibercept	2	(0.1)	2	(0.1)	4	(0.1)
Bevacizumab	1	(0.1)	1	(0.1)	2	(0.1)
Ranibizumab	1	(0.1)	0		1	(0.0)
Bile Acid Sequestrants, C10ac	5	(0.2)	2	(0.1)	7	(0.2)
Colestyramine	4	(0.2)	0		4	(0.1)
Colesevelam	0		1	(0.1)	1	(0.0)
Colestipol	0		1	(0.1)	1	(0.0)
Colestipol Hydrochloride	1	(0.1)	0		1	(0.0)
Combinations Of Oral Blood Glucose Lowering Drugs, A10bd	3	(0.1)	4	(0.2)	7	(0.2)
Metformin Hydrochloride; Sitagliptin Phosphate Monohydrate	1	(0.1)	1	(0.1)	2	(0.1)
Metformin Hydrochloride; Vildagliptin	1	(0.1)	1	(0.1)	2	(0.1)
Glibenclamide; Metformin	1	(0.1)	0		1	(0.0)
Glimepiride; Metformin Hydrochloride	0		1	(0.1)	1	(0.0)
Metformin Hydrochloride; Pioglitazone Hydrochloride	0		1	(0.1)	1	(0.0)
Fatty Acid Derivatives, N03ag	2	(0.1)	5	(0.2)	7	(0.2)
Valproate Sodium	0		5	(0.2)	5	(0.1)
Valproate Magnesium	1	(0.1)	0		1	(0.0)
Valproate Sodium; Valproic Acid	1	(0.1)	0		1	(0.0)
Pyrazolones, N02bb	3	(0.1)	4	(0.2)	7	(0.2)
Metamizole	2	(0.1)	2	(0.1)	4	(0.1)
Metamizole Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Vitamin D Tablet, A11cc04	3	(0.1)	4	(0.2)	7	(0.2)
Calcitriol	3	(0.1)	4	(0.2)	7	(0.2)
Xanthines, R03da	3	(0.1)	4	(0.2)	7	(0.2)
Theophylline	3	(0.1)	4	(0.2)	7	(0.2)
Aromatase Inhibitors, L02bg	4	(0.2)	2	(0.1)	6	(0.1)
Anastrozole	2	(0.1)	1	(0.1)	3	(0.1)
Letrozole	2	(0.1)	1	(0.1)	3	(0.1)
Other Anti-Dementia Drugs, N06dx	3	(0.1)	3	(0.1)	6	(0.1)
Memantine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Apoaequorin	0		2	(0.1)	2	(0.1)
Apoaequorin; Colecalciferol	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Antiglaucoma Preparations, S01ex	3	(0.1)	3	(0.1)	6	(0.1)
Ripasudil Hydrochloride Dihydrate	2	(0.1)	2	(0.1)	4	(0.1)
Netarsudil Mesilate	0		1	(0.1)	1	(0.0)
Omidenepag Isopropyl	1	(0.1)	0		1	(0.0)
Other Drugs Affecting Bone Structure And Mineralization, M05bx	3	(0.1)	3	(0.1)	6	(0.1)
Denosumab	3	(0.1)	3	(0.1)	6	(0.1)
Other Emollients And Protectives, D02ax	5	(0.2)	1	(0.1)	6	(0.1)
Ammonium Lactate	2	(0.1)	1	(0.1)	3	(0.1)
Benzalkonium Chloride; Chlorhexidine Hydrochloride; Isopropyl Myristate; Paraffin, Liquid	2	(0.1)	0		2	(0.1)
Paraffin Soft; Paraffin, Liquid	1	(0.1)	0		1	(0.0)
Other Mineral Products, A12cx	4	(0.2)	2	(0.1)	6	(0.1)
Chromium Picolinate	2	(0.1)	1	(0.1)	3	(0.1)
Boron	2	(0.1)	0		2	(0.1)
Vanadium	2	(0.1)	0		2	(0.1)
Chromium Amino Acid Chelate	0		1	(0.1)	1	(0.0)
Molybdenum	1	(0.1)	0		1	(0.0)
Nickel	1	(0.1)	0		1	(0.0)
Pregnadien Derivatives, G03db	0		6	(0.3)	6	(0.1)
Dienogest	0		4	(0.2)	4	(0.1)
Dydrogesterone	0		2	(0.1)	2	(0.1)
Pregnen (4) Derivatives, G03da	4	(0.2)	2	(0.1)	6	(0.1)
Progesterone	4	(0.2)	2	(0.1)	6	(0.1)
Anticholinesterases, N06da	4	(0.2)	1	(0.1)	5	(0.1)
Rivastigmine	2	(0.1)	0		2	(0.1)
Donepezil	0		1	(0.1)	1	(0.0)
Donepezil Hydrochloride	1	(0.1)	0		1	(0.0)
Ipidacrine	1	(0.1)	0		1	(0.0)
Beta Blocking Agents And Calcium Channel Blockers, C07fb	2	(0.1)	3	(0.1)	5	(0.1)
Atenolol; Nitrendipine	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Bisoprolol Fumarate	0		1	(0.1)	1	(0.0)
Amlodipine Besilate; Carvedilol	1	(0.1)	0		1	(0.0)
Cilnidipine; Nebivolol	0		1	(0.1)	1	(0.0)
Drugs Used In Nicotine Dependence, N07ba	2	(0.1)	3	(0.1)	5	(0.1)
Varenicline Tartrate	2	(0.1)	2	(0.1)	4	(0.1)
Nicotine	0		1	(0.1)	1	(0.0)
Intrauterine Contraceptives, G02ba	2	(0.1)	3	(0.1)	5	(0.1)
Intrauterine Contraceptive Device	2	(0.1)	3	(0.1)	5	(0.1)
Nitrofuran Derivatives, J01xe	4	(0.2)	1	(0.1)	5	(0.1)
Nitrofurantoin	4	(0.2)	1	(0.1)	5	(0.1)
Other Drugs For Functional Gastrointestinal Disorders, A03ax	1	(0.1)	4	(0.2)	5	(0.1)
Simeticone	1	(0.1)	1	(0.1)	2	(0.1)
Aluminium Hydroxide-Magnesium Carbonate Gel; Dimeticone; Magnesium Hydroxide; Silicon Dioxide, Colloidal	0		1	(0.1)	1	(0.0)
Pinaverium	0		1	(0.1)	1	(0.0)
Pinaverium Bromide	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Sclerosing Agents, C05bx	3	(0.1)	2	(0.1)	5	(0.1)
Calcium Dobesilate	3	(0.1)	2	(0.1)	5	(0.1)
Penicillins With Extended Spectrum, J01ca	3	(0.1)	2	(0.1)	5	(0.1)
Amoxicillin	3	(0.1)	2	(0.1)	5	(0.1)
Antiinflammatory Preparations, Non-Steroids For Topical Use, M02aa	3	(0.1)	1	(0.1)	4	(0.1)
Felbinac	2	(0.1)	1	(0.1)	3	(0.1)
Esflurbiprofen; Mentha Spp. Oil	1	(0.1)	0		1	(0.0)
Antivirals For Treatment Of Hiv Infections, Combinations, J05ar	3	(0.1)	1	(0.1)	4	(0.1)
Dolutegravir Sodium; Rilpivirine Hydrochloride	1	(0.1)	0		1	(0.0)
Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Alafenamide Fumarate	1	(0.1)	0		1	(0.0)
Emtricitabine; Tenofovir Disoproxil Fumarate	1	(0.1)	0		1	(0.0)
Lamivudine; Zidovudine	0		1	(0.1)	1	(0.0)
Benzamides, N05al	0		4	(0.2)	4	(0.1)
Levosulpiride	0		2	(0.1)	2	(0.1)
Amisulpride	0		1	(0.1)	1	(0.0)
Tiapride	0		1	(0.1)	1	(0.0)
Beta Blocking Agents, Selective, And Thiazides, C07bb	2	(0.1)	2	(0.1)	4	(0.1)
Bisoprolol Fumarate; Hydrochlorothiazide	2	(0.1)	1	(0.1)	3	(0.1)
Hydrochlorothiazide; Metoprolol Succinate	0		1	(0.1)	1	(0.0)
Bulk-Forming Laxatives, A06ac	2	(0.1)	2	(0.1)	4	(0.1)
Polycarbophil Calcium	2	(0.1)	2	(0.1)	4	(0.1)
Calcineurin Inhibitors, L04ad	3	(0.1)	1	(0.1)	4	(0.1)
Ciclosporin	3	(0.1)	1	(0.1)	4	(0.1)
Corticosteroids, Potent (Group Iii), D07ac	3	(0.1)	1	(0.1)	4	(0.1)
Diflorasone Diacetate	1	(0.1)	0		1	(0.0)
Diflucortolone Valerate	1	(0.1)	0		1	(0.0)
Fludroxycortide	1	(0.1)	0		1	(0.0)
Methylprednisolone Aceponate	0		1	(0.1)	1	(0.0)
Epinephrine, C01ca24	0		4	(0.2)	4	(0.1)
Epinephrine	0		4	(0.2)	4	(0.1)
Expectorants, R05ca	2	(0.1)	2	(0.1)	4	(0.1)
Guaifenesin	2	(0.1)	2	(0.1)	4	(0.1)
Glucocorticoids, H02ab	2	(0.1)	2	(0.1)	4	(0.1)
Prednisone	1	(0.1)	1	(0.1)	2	(0.1)
Deflazacort	1	(0.1)	0		1	(0.0)
Prednisolone Valeroacetate	0		1	(0.1)	1	(0.0)
Interleukin Inhibitors, L04ac	2	(0.1)	2	(0.1)	4	(0.1)
Guselkumab	1	(0.1)	0		1	(0.0)
Ixekizumab	0		1	(0.1)	1	(0.0)
Risankizumab	0		1	(0.1)	1	(0.0)
Secukinumab	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Iron In Other Combinations, B03ae	2	(0.1)	2	(0.1)	4	(0.1)
Ascorbic Acid; Cyanocobalamin; Folic Acid; Iron	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Cyanocobalamin; Folic Acid; Iron; Pyridoxine Hydrochloride	1	(0.1)	0		1	(0.0)
Folic Acid; Iron; Zinc Sulfate	0		1	(0.1)	1	(0.0)
Liver Therapy, A05ba	3	(0.1)	1	(0.1)	4	(0.1)
Choline	1	(0.1)	0		1	(0.0)
Dimethyl 4,4'-Biphenyldicarboxylate	0		1	(0.1)	1	(0.0)
Ornithine Aspartate	1	(0.1)	0		1	(0.0)
Phospholipids Soybean	1	(0.1)	0		1	(0.0)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors, J05af	2	(0.1)	2	(0.1)	4	(0.1)
Emtricitabine	1	(0.1)	1	(0.1)	2	(0.1)
Entecavir	1	(0.1)	1	(0.1)	2	(0.1)
Tenofovir	0		1	(0.1)	1	(0.0)
Tenofovir Alafenamide	1	(0.1)	0		1	(0.0)
Ovulation Stimulants, Synthetic, G03gb	1	(0.1)	3	(0.1)	4	(0.1)
Clomifene	0		2	(0.1)	2	(0.1)
Clomifene Citrate	1	(0.1)	1	(0.1)	2	(0.1)
Phosphodiesterase Inhibitors, C01ce	3	(0.1)	1	(0.1)	4	(0.1)
Milrinone	3	(0.1)	1	(0.1)	4	(0.1)
Preparations Increasing Uric Acid Excretion, M04ab	2	(0.1)	2	(0.1)	4	(0.1)
Benzbromarone	2	(0.1)	2	(0.1)	4	(0.1)
Selective Estrogen Receptor Modulators, G03xc	2	(0.1)	2	(0.1)	4	(0.1)
Bazedoxifene Acetate	0		1	(0.1)	1	(0.0)
Ormeloxifene	1	(0.1)	0		1	(0.0)
Raloxifene	0		1	(0.1)	1	(0.0)
Raloxifene Hydrochloride	1	(0.1)	0		1	(0.0)
Soft Paraffin And Fat Products, D02ac	2	(0.1)	2	(0.1)	4	(0.1)
White Soft Paraffin	1	(0.1)	2	(0.1)	3	(0.1)
Isopropyl Myristate; Paraffin, Liquid	1	(0.1)	0		1	(0.0)
Vitamin K, B02ba	4	(0.2)	0		4	(0.1)
Vitamin K Nos	4	(0.2)	0		4	(0.1)
Adrenergic And Dopaminergic Agents, C01ca	2	(0.1)	1	(0.1)	3	(0.1)
Midodrine	1	(0.1)	1	(0.1)	2	(0.1)
Midodrine Hydrochloride	1	(0.1)	0		1	(0.0)
Amino Acids, Incl. Combinations With Polypeptides, V06dd	1	(0.1)	2	(0.1)	3	(0.1)
Aspartic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Antiarrhythmics, Class Ib, C01bb02	1	(0.1)	2	(0.1)	3	(0.1)
Mexiletine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Bile Therapy, A05a	2	(0.1)	1	(0.1)	3	(0.1)
Timonacic	2	(0.1)	1	(0.1)	3	(0.1)
Calcium Channel Blockers And Diuretics, C08ga	3	(0.1)	0		3	(0.1)
Amlodipine Besilate; Indapamide	3	(0.1)	0		3	(0.1)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Corticosteroids, Potent, Other Combinations, D07xc	1	(0.1)	2	(0.1)	3	(0.1)
Betamethasone Dipropionate; Salicylic Acid	1	(0.1)	1	(0.1)	2	(0.1)
Mometasone Furoate; Salicylic Acid	0		1	(0.1)	1	(0.0)
General Nutrients, V06	1	(0.1)	2	(0.1)	3	(0.1)
General Nutrients	1	(0.1)	2	(0.1)	3	(0.1)
Indole Derivatives, N05ae	2	(0.1)	1	(0.1)	3	(0.1)
Lurasidone Hydrochloride	2	(0.1)	0		2	(0.1)
Ziprasidone	0		1	(0.1)	1	(0.0)
Iron Trivalent, Oral Preparations, B03ab	2	(0.1)	1	(0.1)	3	(0.1)
Ferric Hydroxide Polymaltose Complex	2	(0.1)	1	(0.1)	3	(0.1)
Monoamine Oxidase B Inhibitors, N04bd	2	(0.1)	1	(0.1)	3	(0.1)
Rasagiline Mesylate	1	(0.1)	1	(0.1)	2	(0.1)
Rasagiline	1	(0.1)	0		1	(0.0)
Mucolytics, R05cb	1	(0.1)	2	(0.1)	3	(0.1)
Carbocisteine	1	(0.1)	1	(0.1)	2	(0.1)
L-Carbocisteine	0		1	(0.1)	1	(0.0)
Multivitamins, Combinations, A11a	3	(0.1)	0		3	(0.1)
Multivitamins, Combinations	3	(0.1)	0		3	(0.1)
Other Alimentary Tract And Metabolism Products, A16a	1	(0.1)	2	(0.1)	3	(0.1)
Clostridium Butyricum	1	(0.1)	2	(0.1)	3	(0.1)
Other Antiallergics, S01gx	1	(0.1)	2	(0.1)	3	(0.1)
Acitazanolast	1	(0.1)	2	(0.1)	3	(0.1)
Other Capillary Stabilizing Agents, C05cx	3	(0.1)	0		3	(0.1)
Hesperidin	3	(0.1)	0		3	(0.1)
Other Hypnotics And Sedatives, N05cm	0		3	(0.1)	3	(0.1)
Suvorexant	0		2	(0.1)	2	(0.1)
Lemborexant	0		1	(0.1)	1	(0.0)
Other Peripheral Vasodilators, C04ax	1	(0.1)	2	(0.1)	3	(0.1)
Naftidrofuryl Oxalate	1	(0.1)	2	(0.1)	3	(0.1)
Other Systemic Hemostatics, B02bx	2	(0.1)	1	(0.1)	3	(0.1)
Carbazochrome Sodium Sulfonate	2	(0.1)	1	(0.1)	3	(0.1)
Other Therapeutic Products, V03ax	2	(0.1)	1	(0.1)	3	(0.1)
Bee Pollen	1	(0.1)	0		1	(0.0)
Bromelains; Quercetin	1	(0.1)	0		1	(0.0)
Other Therapeutic Products	0		1	(0.1)	1	(0.0)
Salicylic Acid And Derivatives, N02ba	1	(0.1)	2	(0.1)	3	(0.1)
Acetylsalicylic Acid; Calcium Carbonate	0		1	(0.1)	1	(0.0)
Salicylic Acid And Derivatives	0		1	(0.1)	1	(0.0)
Salsalate	1	(0.1)	0		1	(0.0)
Thiouracils, H03ba	3	(0.1)	0		3	(0.1)
Propylthiouracil	3	(0.1)	0		3	(0.1)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Agents For Dermatitis, Excluding Corticosteroids, D11ah	1	(0.1)	1	(0.1)	2	(0.1)
Pimecrolimus	0		1	(0.1)	1	(0.0)
Tralokinumab	1	(0.1)	0		1	(0.0)
Antiandrogens, Plain, G03ha	1	(0.1)	1	(0.1)	2	(0.1)
Cyproterone	0		1	(0.1)	1	(0.0)
Cyproterone Acetate	1	(0.1)	0		1	(0.0)
Antidiarrheal Microorganisms, A07f	1	(0.1)	1	(0.1)	2	(0.1)
Antidiarrheal Microorganisms	1	(0.1)	1	(0.1)	2	(0.1)
Antihypertensives, C02	1	(0.1)	1	(0.1)	2	(0.1)
Antihypertensives	1	(0.1)	1	(0.1)	2	(0.1)
Barbiturates And Derivatives, N03aa	2	(0.1)	0		2	(0.1)
Primidone	2	(0.1)	0		2	(0.1)
Barbiturates, Plain, N05ca	1	(0.1)	1	(0.1)	2	(0.1)
Butalbital	1	(0.1)	1	(0.1)	2	(0.1)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds, A03bb	2	(0.1)	0		2	(0.1)
Hyoscine Butylbromide	2	(0.1)	0		2	(0.1)
Butyrophenone Derivatives, N05ad	2	(0.1)	0		2	(0.1)
Haloperidol	2	(0.1)	0		2	(0.1)
Calcitonin Gene-Related Peptide (Cgrp) Antagonists, N02cd	2	(0.1)	0		2	(0.1)
Erenumab Aooe	2	(0.1)	0		2	(0.1)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds, A02ad	1	(0.1)	1	(0.1)	2	(0.1)
Aluminium Hydroxide Gel; Magnesium Hydroxide	1	(0.1)	0		1	(0.0)
Aluminium Hydroxide; Magnesium Hydroxide	0		1	(0.1)	1	(0.0)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives, J01ee	0		2	(0.1)	2	(0.1)
Sulfamethoxazole; Trimethoprim	0		2	(0.1)	2	(0.1)
Corticosteroids, Plain, S01ba	1	(0.1)	1	(0.1)	2	(0.1)
Loteprednol Etabonate	1	(0.1)	1	(0.1)	2	(0.1)
Dopa And Dopa Derivatives, N04ba	2	(0.1)	0		2	(0.1)
Benserazide Hydrochloride; Levodopa	1	(0.1)	0		1	(0.0)
Carbidopa	1	(0.1)	0		1	(0.0)
Levodopa	1	(0.1)	0		1	(0.0)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02b	0		2	(0.1)	2	(0.1)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	0		1	(0.1)	1	(0.0)
Teprenone	0		1	(0.1)	1	(0.0)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia, V03ae	2	(0.1)	0		2	(0.1)
Calcium Polystyrene Sulfonate	1	(0.1)	0		1	(0.0)
Sodium Polystyrene Sulfonate	1	(0.1)	0		1	(0.0)
Heparins Or Heparinoids For Topical Use, C05ba	1	(0.1)	1	(0.1)	2	(0.1)
Heparins Or Heparinoids For Topical Use	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
High-Ceiling Diuretics And Potassium-Sparing Agents, C03eb	1	(0.1)	1	(0.1)	2	(0.1)
Eplerenone; Torasemide	0		1	(0.1)	1	(0.0)
Furosemide; Spironolactone	1	(0.1)	0		1	(0.0)
Methyldopa, C02ab	0		2	(0.1)	2	(0.1)
Methyldopa	0		2	(0.1)	2	(0.1)
Non-Nucleoside Reverse Transcriptase Inhibitors, J05ag	0		2	(0.1)	2	(0.1)
Efavirenz	0		1	(0.1)	1	(0.0)
Rilpivirine	0		1	(0.1)	1	(0.0)
Other Analgesics And Antipyretics, N02bg	1	(0.1)	1	(0.1)	2	(0.1)
Gabapentin; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Mirogabalin Besilate	1	(0.1)	0		1	(0.0)
Other Antiemetics, A04ad	1	(0.1)	1	(0.1)	2	(0.1)
Difenidol Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Other Combinations Of Nutrients, V06dx	1	(0.1)	1	(0.1)	2	(0.1)
Amino Acids Nos; Capsicum Annuum Fruit; Chlorella Vulgaris; Cordyceps Sinensis; Ganoderma Lucidum; Inositol; Lentinus Edodes; Magnesium; Potassium; Pycnogenol; Rhodiola Rosea Root	0		1	(0.1)	1	(0.0)
Other Combinations Of Nutrients	1	(0.1)	0		1	(0.0)
Other Cough Suppressants, R05db	1	(0.1)	1	(0.1)	2	(0.1)
Benzonatate	1	(0.1)	1	(0.1)	2	(0.1)
Other Drugs Used In Benign Prostatic Hypertrophy, G04cx	2	(0.1)	0		2	(0.1)
Cernitin Gbx	1	(0.1)	0		1	(0.0)
Cucurbita Pepo Seed; Epilobium Parviflorum; Lycopene; Pyridoxine Hydrochloride; Serenoa Repens; Urtica Dioica Leaf; Vitamin E Nos; Zinc	1	(0.1)	0		1	(0.0)
Other Mineral Supplements, A12c	0		2	(0.1)	2	(0.1)
Magnesium Oxide; Zinc Sulfate	0		1	(0.1)	1	(0.0)
Magnesium; Zinc	0		1	(0.1)	1	(0.0)
Other Nervous System Drugs, N07xx	2	(0.1)	0		2	(0.1)
Dextromethorphan Hydrobromide; Quinidine Sulfate	1	(0.1)	0		1	(0.0)
Fampridine	1	(0.1)	0		1	(0.0)
Other Nutrients, V06d	1	(0.1)	1	(0.1)	2	(0.1)
Omega-7 Fatty Acids Nos	0		1	(0.1)	1	(0.0)
Other Nutrients	1	(0.1)	0		1	(0.0)
Phenothiazines With Aliphatic Side-Chain, N05aa	0		2	(0.1)	2	(0.1)
Levomepromazine	0		1	(0.1)	1	(0.0)
Levomepromazine Maleate	0		1	(0.1)	1	(0.0)
Phenylpiperidine Derivatives, N02ab	2	(0.1)	0		2	(0.1)
Fentanyl	2	(0.1)	0		2	(0.1)
Preparations With Salicylic Acid Derivatives, M02ac	2	(0.1)	0		2	(0.1)
Borneol; Camphor; Diphenhydramine; Glycol Salicylate; Menthol; Methyl Salicylate; Squalene; Thymol	1	(0.1)	0		1	(0.0)
Trolamine Salicylate	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Protein Supplements, V06b	1	(0.1)	1	(0.1)	2	(0.1)
Protein Supplements	0		1	(0.1)	1	(0.0)
Soy Protein	1	(0.1)	0		1	(0.0)
Pyrimidine Derivatives, C02dc	0		2	(0.1)	2	(0.1)
Minoxidil	0		2	(0.1)	2	(0.1)
Silicone Products, D02aa	1	(0.1)	1	(0.1)	2	(0.1)
Dimeticone; Silicones Nos	0		1	(0.1)	1	(0.0)
Silicon	1	(0.1)	0		1	(0.0)
Sympathomimetics, Combinations Excl. Corticosteroids, R01ab	1	(0.1)	1	(0.1)	2	(0.1)
Benzethonium Chloride; Chlorphenamine Maleate; Lidocaine; Naphazoline Hydrochloride	1	(0.1)	0		1	(0.0)
Calcium Propionate; Naphazoline Nitrate	0		1	(0.1)	1	(0.0)
Synthetic Anticholinergics, Quaternary Ammonium Compounds, A03ab	1	(0.1)	1	(0.1)	2	(0.1)
Clidinium Bromide	0		1	(0.1)	1	(0.0)
Otilonium	1	(0.1)	0		1	(0.0)
Third-Generation Cephalosporins, J01dd	0		2	(0.1)	2	(0.1)
Cefdinir	0		2	(0.1)	2	(0.1)
Tonics, A13a	2	(0.1)	0		2	(0.1)
Dietary Supplement	2	(0.1)	0		2	(0.1)
Vitamin B-Complex With Minerals, A11ec	2	(0.1)	0		2	(0.1)
Vitamin B Complex; Zinc	1	(0.1)	0		1	(0.0)
Yeast Dried	1	(0.1)	0		1	(0.0)
Vitamin B-Complex With Vitamin C, A11eb	0		2	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Nicotinic Acid; Pantothenic Acid; Pyridoxine Hydrochloride; Riboflavin; Thiamine	0		1	(0.1)	1	(0.0)
Vitamin B-Complex, Incl. Combinations, A11e	1	(0.1)	1	(0.1)	2	(0.1)
Vitamin B-Complex, Incl. Combinations	1	(0.1)	1	(0.1)	2	(0.1)
Amides, N01bb	1	(0.1)	0		1	(0.0)
Ropivacaine Hydrochloride	1	(0.1)	0		1	(0.0)
Amino Acids And Derivatives, A16aa	0		1	(0.1)	1	(0.0)
Carnitine Orotate	0		1	(0.1)	1	(0.0)
Analgesics, N02	0		1	(0.1)	1	(0.0)
Analgesics	0		1	(0.1)	1	(0.0)
Antacids With Sodium Bicarbonate, A02ah	0		1	(0.1)	1	(0.0)
Aluminium Hydroxide Gel, Dried; Calcium Carbonate; Lipase; Magnesium Carbonate; Sodium Bicarbonate	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Antacids, Other Combinations, A02ax	1	(0.1)	0		1	(0.0)
Aluminium Silicate; Calcium Carbonate; Cinnamomum Spp. Bark; Citrus Deliciosa Peel; Diastase; Foeniculum Vulgare; Gentiana Lutea Root; Magnesium Carbonate; Myristica Fragrans; Picrasma Quassioides Wood; Sodium	1	(0.1)	0		1	(0.0)
Anti-Androgens, L02bb	0		1	(0.1)	1	(0.0)
Bicalutamide	0		1	(0.1)	1	(0.0)
Anti-Estrogens, L02ba	1	(0.1)	0		1	(0.0)
Tamoxifen Citrate	1	(0.1)	0		1	(0.0)
Antiandrogens And Estrogens, G03hb	0		1	(0.1)	1	(0.0)
Cyproterone Acetate; Ethinylestradiol	0		1	(0.1)	1	(0.0)
Anticholinergics, S01fa	1	(0.1)	0		1	(0.0)
Hydroxyamfetamine Hydrobromide; Tropicamide	1	(0.1)	0		1	(0.0)
Antidepressants In Combination With Psycholeptics, N06ca	0		1	(0.1)	1	(0.0)
Flupentixol Dihydrochloride; Melitracen Hydrochloride	0		1	(0.1)	1	(0.0)
Antifungals For Topical Use, D01a	1	(0.1)	0		1	(0.0)
Liranaftate	1	(0.1)	0		1	(0.0)
Antiinfectives For Treatment Of Acne, D10af	0		1	(0.1)	1	(0.0)
Nadifloxacin	0		1	(0.1)	1	(0.0)
Antiinflammatory And Antirheumatic Products, Non-Steroids, M01a	0		1	(0.1)	1	(0.0)
Antiinflammatory And Antirheumatic Products, Non-Steroids	0		1	(0.1)	1	(0.0)
Antivaricose Therapy, C05b	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Quercetin	1	(0.1)	0		1	(0.0)
Antivirals, D06bb	0		1	(0.1)	1	(0.0)
Imiquimod	0		1	(0.1)	1	(0.0)
Antracen Derivatives, D05ac	1	(0.1)	0		1	(0.0)
Dithranol	1	(0.1)	0		1	(0.0)
Ascorbic Acid (Vitamin C), Combinations, A11gb	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Calcium; Zinc	1	(0.1)	0		1	(0.0)
Bile And Liver Therapy, A05	1	(0.1)	0		1	(0.0)
Bicyclol	1	(0.1)	0		1	(0.0)
Blood Glucose Lowering Drugs, Excl. Insulins, A10b	0		1	(0.1)	1	(0.0)
Chromium Picolinate; Cinnamomum Verum Bark; Colecalciferol	0		1	(0.1)	1	(0.0)
Centrally Acting Antiobesity Products, A08aa	0		1	(0.1)	1	(0.0)
Phentermine	0		1	(0.1)	1	(0.0)
Charcoal Preparations, A07ba	1	(0.1)	0		1	(0.0)
Ast 120	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Choline Esters, N07ab	0		1	(0.1)	1	(0.0)
Bethanechol Chloride	0		1	(0.1)	1	(0.0)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors, J01cr	0		1	(0.1)	1	(0.0)
Amoxicillin Trihydrate; Clavulanate Potassium	0		1	(0.1)	1	(0.0)
Combinations Of Vitamins, A11ja	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Dl-Alpha Tocopheryl Acetate; Fursultiamine; Hydroxocobalamin Acetate; Pyridoxal Phosphate; Riboflavin Tetrabutyrate	1	(0.1)	0		1	(0.0)
Corticosteroids And Antiinfectives In Combination, S01ca	0		1	(0.1)	1	(0.0)
Loteprednol Etabonate; Tobramycin	0		1	(0.1)	1	(0.0)
Corticosteroids, Moderately Potent (Group Ii), D07ab	0		1	(0.1)	1	(0.0)
Dexamethasone Propionate	0		1	(0.1)	1	(0.0)
Corticosteroids, Moderately Potent, Combinations With Antiseptics, D07bb	0		1	(0.1)	1	(0.0)
Chlorocresol; Clobetasone Butyrate	0		1	(0.1)	1	(0.0)
Corticosteroids, Moderately Potent, Other Combinations, D07xb	1	(0.1)	0		1	(0.0)
Coal Tar; Dexamethasone	1	(0.1)	0		1	(0.0)
Dantrolene And Derivatives, M03ca	0		1	(0.1)	1	(0.0)
Dantrolene Sodium	0		1	(0.1)	1	(0.0)
Drugs Used In Erectile Dysfunction, G04be	0		1	(0.1)	1	(0.0)
Alprostadil; Papaverine; Phentolamine	0		1	(0.1)	1	(0.0)
Emollients And Protectives, D02a	0		1	(0.1)	1	(0.0)
Omega-6 Fatty Acids	0		1	(0.1)	1	(0.0)
Enemas, A06ag	1	(0.1)	0		1	(0.0)
Sodium Citrate; Sodium Lauryl Sulfoacetate	1	(0.1)	0		1	(0.0)
Ethers Chemically Close To Antihistamines, N04ab	1	(0.1)	0		1	(0.0)
Orphenadrine Hydrochloride	1	(0.1)	0		1	(0.0)
Hormonal Contraceptives For Systemic Use, G03a	1	(0.1)	0		1	(0.0)
Oral Contraceptive Nos	1	(0.1)	0		1	(0.0)
Immunoglobulins, J06b	1	(0.1)	0		1	(0.0)
Immunoglobulins Nos	1	(0.1)	0		1	(0.0)
Integrase Inhibitors, J05aj	1	(0.1)	0		1	(0.0)
Bictegravir	1	(0.1)	0		1	(0.0)
Interferons, L03ab	1	(0.1)	0		1	(0.0)
Interferon Beta-1a	1	(0.1)	0		1	(0.0)
Long-Acting Sulfonamides, J01ed	1	(0.1)	0		1	(0.0)
Sulfamethoxypyridazine	1	(0.1)	0		1	(0.0)
Macrolides, J01fa	1	(0.1)	0		1	(0.0)
Roxithromycin	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Mineral Supplements, A12	0		1	(0.1)	1	(0.0)
Mineral Supplements	0		1	(0.1)	1	(0.0)
Monoamine Oxidase A Inhibitors, N06ag	1	(0.1)	0		1	(0.0)
Moclobemide	1	(0.1)	0		1	(0.0)
Nasal Preparations, R01	1	(0.1)	0		1	(0.0)
Nasal Preparations	1	(0.1)	0		1	(0.0)
Ophthalmologicals, S01	0		1	(0.1)	1	(0.0)
Ophthalmologicals	0		1	(0.1)	1	(0.0)
Opioids In Combination With Antispasmodics, N02ag	1	(0.1)	0		1	(0.0)
Atropa Belladonna Extract; Caffeine; Papaver Somniferum Tincture; Paracetamol	1	(0.1)	0		1	(0.0)
Opium Derivatives And Expectorants, R05fa	0		1	(0.1)	1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin	0		1	(0.1)	1	(0.0)
Other Anti-Parathyroid Agents, H05bx	0		1	(0.1)	1	(0.0)
Cinacalcet	0		1	(0.1)	1	(0.0)
Other Antifungals For Topical Use, D01ae	0		1	(0.1)	1	(0.0)
Naftifine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antiinflammatory/Antirheumatic Agents In Combination With Other Drugs, M01bx	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Boron; Boswellia Serrata; Chondroitin; Gelatine Hydrolysate; Glucosamine; Hyaluronic Acid; Manganese; Methylsulfonylmethane	1	(0.1)	0		1	(0.0)
Other Antimigraine Preparations, N02cx	0		1	(0.1)	1	(0.0)
Lomerizine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Anxiolytics, N05bx	1	(0.1)	0		1	(0.0)
Etifoxine Hydrochloride	1	(0.1)	0		1	(0.0)
Other Cardiac Combination Products, C01ex	1	(0.1)	0		1	(0.0)
Other Cardiac Combination Products	1	(0.1)	0		1	(0.0)
Other Cicatrizants, D03ax	1	(0.1)	0		1	(0.0)
Cadexomer Iodine	1	(0.1)	0		1	(0.0)
Other Dermatologicals, D11ax	0		1	(0.1)	1	(0.0)
Paraffin, Liquid; Polyethylene Resin	0		1	(0.1)	1	(0.0)
Other Estrogens, G03cx	0		1	(0.1)	1	(0.0)
Tibolone	0		1	(0.1)	1	(0.0)
Other Immunostimulants, L03ax	0		1	(0.1)	1	(0.0)
Transfer Factor	0		1	(0.1)	1	(0.0)
Other Parasympathomimetics, N07ax	0		1	(0.1)	1	(0.0)
Choline Alfoscerate	0		1	(0.1)	1	(0.0)
Other Urologicals, G04bx	0		1	(0.1)	1	(0.0)
Alanine; Copper; Cucurbita Spp.; Glutamic Acid; Glycine; Serenoa Repens Fruit; Urtica Dioica Leaf; Zinc	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Peripheral Opioid Receptor Antagonists, A06ah	0		1	(0.1)	1	(0.0)
Naloxegol Oxalate	0		1	(0.1)	1	(0.0)
Peroxides, D10ae	0		1	(0.1)	1	(0.0)
Benzoyl Peroxide	0		1	(0.1)	1	(0.0)
Phenol And Derivatives, D08ae	1	(0.1)	0		1	(0.0)
Cresol; Zinc Oxide	1	(0.1)	0		1	(0.0)
Phenylephrine, C01ca06	0		1	(0.1)	1	(0.0)
Phenylephrine Hydrochloride	0		1	(0.1)	1	(0.0)
Progestogens And Estrogens, Fixed Combinations, G03fa	1	(0.1)	0		1	(0.0)
Estrogen Nos; Progesterone	1	(0.1)	0		1	(0.0)
Prostaglandins, C01ea	0		1	(0.1)	1	(0.0)
Alprostadil	0		1	(0.1)	1	(0.0)
Psychostimulants, Agents Used For Adhd And Nootropics, N06b	1	(0.1)	0		1	(0.0)
Coffea Arabica; Cyanocobalamin; Folic Acid; Phosphatidyl Serine; Pyridoxine Hydrochloride	1	(0.1)	0		1	(0.0)
Pyrimidine Analogues, L01bc	1	(0.1)	0		1	(0.0)
Fluorouracil	1	(0.1)	0		1	(0.0)
Retinoids For Treatment Of Psoriasis, D05bb	0		1	(0.1)	1	(0.0)
Acitretin	0		1	(0.1)	1	(0.0)
Second-Generation Cephalosporins, J01dc	0		1	(0.1)	1	(0.0)
Cefaclor	0		1	(0.1)	1	(0.0)
Substituted Alkylamines, R06ab	1	(0.1)	0		1	(0.0)
Dexchlorpheniramine Maleate	1	(0.1)	0		1	(0.0)
Thioxanthene Derivatives, N05af	1	(0.1)	0		1	(0.0)
Flupentixol	1	(0.1)	0		1	(0.0)
Trimethoprim And Derivatives, J01ea	0		1	(0.1)	1	(0.0)
Trimethoprim	0		1	(0.1)	1	(0.0)
Viral Vaccines, J07b	0		1	(0.1)	1	(0.0)
Viral Vaccines	0		1	(0.1)	1	(0.0)
Zinc Products, D02ab	1	(0.1)	0		1	(0.0)
Menthol; Zinc Oxide	1	(0.1)	0		1	(0.0)
Zinc, A12cb	0		1	(0.1)	1	(0.0)
Zinc Orotate	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.1.25 Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	1880		1878		3758	
All medications	1880	(100.0)	1877	(100.0)	3757	(100.0)
Biguanides, A10ba	1626	(86.5)	1601	(85.2)	3227	(85.9)
Metformin	1176	(62.5)	1130	(60.2)	2306	(61.4)
Metformin Hydrochloride	458	(24.4)	478	(25.4)	936	(24.9)
Metformin Embonate	2	(0.1)	1	(0.1)	3	(0.1)
Hmg Coa Reductase Inhibitors, C10aa	1179	(62.7)	1147	(61.1)	2326	(61.9)
Atorvastatin	396	(21.1)	394	(21.0)	790	(21.0)
Rosuvastatin Calcium	181	(9.6)	192	(10.2)	373	(9.9)
Rosuvastatin	175	(9.3)	175	(9.3)	350	(9.3)
Atorvastatin Calcium	174	(9.3)	174	(9.3)	348	(9.3)
Simvastatin	147	(7.8)	120	(6.4)	267	(7.1)
Pravastatin	48	(2.5)	33	(1.8)	81	(2.2)
Pitavastatin Calcium	38	(2.0)	32	(1.7)	70	(1.9)
Pravastatin Sodium	9	(0.5)	16	(0.8)	25	(0.7)
Lovastatin	4	(0.2)	8	(0.4)	12	(0.3)
Pitavastatin	6	(0.3)	4	(0.2)	10	(0.3)
Fluvastatin Sodium	1	(0.1)	3	(0.2)	4	(0.1)
Fluvastatin	3	(0.2)	0		3	(0.1)
Atorvastatin Calcium Trihydrate	0		1	(0.1)	1	(0.0)
Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors, A10bk	711	(37.8)	674	(35.9)	1385	(36.9)
Empagliflozin	326	(17.3)	285	(15.2)	611	(16.3)
Dapagliflozin	157	(8.3)	148	(7.9)	305	(8.1)
Dapagliflozin Propanediol Monohydrate	107	(5.7)	117	(6.2)	224	(6.0)
Canagliflozin	83	(4.4)	90	(4.8)	173	(4.6)
Ipragliflozin L-Proline	13	(0.7)	16	(0.8)	29	(0.8)
Tofogliflozin	11	(0.6)	5	(0.3)	16	(0.4)
Ipragliflozin	5	(0.3)	4	(0.2)	9	(0.2)
Ertugliflozin	5	(0.3)	3	(0.2)	8	(0.2)
Luseogliflozin	4	(0.2)	3	(0.2)	7	(0.2)
Ertugliflozin Pidolate	0		5	(0.3)	5	(0.1)
Sulfonylureas, A10bb	645	(34.3)	652	(34.7)	1297	(34.5)
Gliclazide	278	(14.8)	290	(15.4)	568	(15.1)
Glimepiride	227	(12.1)	224	(11.9)	451	(12.0)
Glipizide	79	(4.2)	88	(4.7)	167	(4.4)
Glibenclamide	61	(3.2)	49	(2.6)	110	(2.9)
Gliquidone	2	(0.1)	2	(0.1)	4	(0.1)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ace Inhibitors, Plain, C09aa	547	(29.1)	544	(29.0)	1091	(29.0)
Lisinopril	160	(8.5)	167	(8.9)	327	(8.7)
Ramipril	142	(7.5)	127	(6.8)	269	(7.2)
Perindopril	94	(5.0)	134	(7.1)	228	(6.1)
Enalapril	64	(3.4)	48	(2.6)	112	(3.0)
Perindopril Erbumine	32	(1.7)	15	(0.8)	47	(1.2)
Benazepril	15	(0.8)	9	(0.5)	24	(0.6)
Enalapril Maleate	5	(0.3)	9	(0.5)	14	(0.4)
Perindopril Arginine	7	(0.4)	6	(0.3)	13	(0.3)
Trandolapril	9	(0.5)	4	(0.2)	13	(0.3)
Benazepril Hydrochloride	4	(0.2)	2	(0.1)	6	(0.2)
Fosinopril	2	(0.1)	4	(0.2)	6	(0.2)
Lisinopril Dihydrate	2	(0.1)	3	(0.2)	5	(0.1)
Quinapril Hydrochloride	2	(0.1)	3	(0.2)	5	(0.1)
Captopril	2	(0.1)	2	(0.1)	4	(0.1)
Quinapril	1	(0.1)	3	(0.2)	4	(0.1)
Enalaprilat	0		3	(0.2)	3	(0.1)
Imidapril Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Zofenopril Calcium	2	(0.1)	1	(0.1)	3	(0.1)
Fosinopril Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Alacepril	1	(0.1)	0		1	(0.0)
Delapril	0		1	(0.1)	1	(0.0)
Imidapril	1	(0.1)	0		1	(0.0)
Temocapril Hydrochloride	1	(0.1)	0		1	(0.0)
Platelet Aggregation Inhibitors Excl. Heparin, B01ac	534	(28.4)	547	(29.1)	1081	(28.8)
Acetylsalicylic Acid	468	(24.9)	463	(24.6)	931	(24.8)
Clopidogrel Bisulfate	45	(2.4)	40	(2.1)	85	(2.3)
Clopidogrel	45	(2.4)	38	(2.0)	83	(2.2)
Acetylsalicylic Acid; Magnesium Hydroxide	6	(0.3)	12	(0.6)	18	(0.5)
Cilostazol	8	(0.4)	10	(0.5)	18	(0.5)
Ticagrelor	4	(0.2)	6	(0.3)	10	(0.3)
Acetylsalicylic Acid; Magnesium	1	(0.1)	6	(0.3)	7	(0.2)
Acetylsalicylate Lysine	5	(0.3)	1	(0.1)	6	(0.2)
Prasugrel	2	(0.1)	2	(0.1)	4	(0.1)
Sarpogrelate Hydrochloride	0		4	(0.2)	4	(0.1)
Acetylsalicylic Acid; Clopidogrel Bisulfate	0		2	(0.1)	2	(0.1)
Acetylsalicylic Acid; Glycine	1	(0.1)	1	(0.1)	2	(0.1)
Dipyridamole	1	(0.1)	1	(0.1)	2	(0.1)
Prasugrel Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Triflusal	1	(0.1)	1	(0.1)	2	(0.1)
Acetylsalicylic Acid; Aluminium Glycinate; Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Acetylsalicylic Acid; Aluminium Hydroxide; Magnesium Hydroxide	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Magnesium Oxide	0		1	(0.1)	1	(0.0)
Beraprost Sodium	0		1	(0.1)	1	(0.0)
Clopidogrel Napadisilate	0		1	(0.1)	1	(0.0)
Clopidogrel Resinate	1	(0.1)	0		1	(0.0)
Salicylic Acid	1	(0.1)	0		1	(0.0)
Salicylic Acid; Urea	0		1	(0.1)	1	(0.0)
Ticlopidine Hydrochloride	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Angiotensin Ii Receptor Blockers (Arbs), Plain, C09ca	547	(29.1)	521	(27.7)	1068	(28.4)
Losartan	171	(9.1)	167	(8.9)	338	(9.0)
Telmisartan	80	(4.3)	72	(3.8)	152	(4.0)
Valsartan	79	(4.2)	72	(3.8)	151	(4.0)
Irbesartan	46	(2.5)	42	(2.2)	88	(2.3)
Candesartan	43	(2.3)	32	(1.7)	75	(2.0)
Losartan Potassium	35	(1.9)	40	(2.1)	75	(2.0)
Candesartan Cilexetil	26	(1.4)	31	(1.6)	57	(1.5)
Olmesartan	26	(1.4)	23	(1.2)	49	(1.3)
Olmesartan Medoxomil	21	(1.1)	23	(1.2)	44	(1.2)
Azilsartan	16	(0.8)	18	(1.0)	34	(0.9)
Allisartan	1	(0.1)	1	(0.1)	2	(0.1)
Azilsartan Medoxomil	2	(0.1)	0		2	(0.1)
Allisartan Isoproxil	0		1	(0.1)	1	(0.0)
Eprosartan	1	(0.1)	0		1	(0.0)
Eprosartan Mesilate	1	(0.1)	0		1	(0.0)
Irbesartan Hydrochloride	1	(0.1)	0		1	(0.0)
Insulins And Analogues For Injection, Long-Acting, A10ae	519	(27.6)	515	(27.4)	1034	(27.5)
Insulin Glargine	339	(18.0)	334	(17.8)	673	(17.9)
Insulin Degludec	148	(7.9)	140	(7.5)	288	(7.7)
Insulin Detemir	21	(1.1)	24	(1.3)	45	(1.2)
Insulin Glargine Biosimilar 1	11	(0.6)	17	(0.9)	28	(0.8)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors, A10bh	517	(27.5)	495	(26.4)	1012	(26.9)
Sitagliptin	132	(7.0)	123	(6.5)	255	(6.8)
Vildagliptin	119	(6.3)	118	(6.3)	237	(6.3)
Sitagliptin Phosphate	101	(5.4)	99	(5.3)	200	(5.3)
Linagliptin	76	(4.0)	63	(3.4)	139	(3.7)
Teneligliptin Hydrobromide Hydrate	11	(0.6)	23	(1.2)	34	(0.9)
Teneligliptin	12	(0.6)	16	(0.8)	28	(0.8)
Saxagliptin	11	(0.6)	15	(0.8)	26	(0.7)
Alogliptin Benzoate	13	(0.7)	10	(0.5)	23	(0.6)
Alogliptin	10	(0.5)	7	(0.4)	17	(0.5)
Saxagliptin Hydrochloride	9	(0.5)	5	(0.3)	14	(0.4)
Sitagliptin Phosphate Monohydrate	6	(0.3)	5	(0.3)	11	(0.3)
Anagliptin	5	(0.3)	3	(0.2)	8	(0.2)
Teneligliptin Hydrobromide	3	(0.2)	5	(0.3)	8	(0.2)
Gemigliptin	4	(0.2)	0		4	(0.1)
Gemigliptin Tartrate	1	(0.1)	2	(0.1)	3	(0.1)
Omarigliptin	3	(0.2)	0		3	(0.1)
Evogliptin	1	(0.1)	1	(0.1)	2	(0.1)
Evogliptin Tartrate	1	(0.1)	0		1	(0.0)
Beta Blocking Agents, Selective, C07ab	471	(25.1)	423	(22.5)	894	(23.8)
Bisoprolol	95	(5.0)	95	(5.1)	190	(5.1)
Metoprolol	94	(5.0)	91	(4.8)	185	(4.9)
Bisoprolol Fumarate	90	(4.8)	75	(4.0)	165	(4.4)
Atenolol	43	(2.3)	31	(1.6)	74	(2.0)
Metoprolol Succinate	38	(2.0)	36	(1.9)	74	(2.0)
Nebivolol Hydrochloride	41	(2.2)	31	(1.6)	72	(1.9)
Nebivolol	37	(2.0)	30	(1.6)	67	(1.8)
Metoprolol Tartrate	22	(1.2)	23	(1.2)	45	(1.2)
Betaxolol Hydrochloride	5	(0.3)	11	(0.6)	16	(0.4)
Betaxolol	5	(0.3)	1	(0.1)	6	(0.2)
Celiprolol Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Beta Blocking Agents	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dihydropyridine Derivatives, C08ca	432	(23.0)	389	(20.7)	821	(21.9)
Amlodipine	262	(13.9)	254	(13.5)	516	(13.7)
Amlodipine Besilate	89	(4.7)	73	(3.9)	162	(4.3)
Nifedipine	28	(1.5)	24	(1.3)	52	(1.4)
Lercanidipine Hydrochloride	12	(0.6)	7	(0.4)	19	(0.5)
Lercanidipine	14	(0.7)	1	(0.1)	15	(0.4)
Felodipine	5	(0.3)	4	(0.2)	9	(0.2)
Lacidipine	7	(0.4)	1	(0.1)	8	(0.2)
Azelnidipine	2	(0.1)	4	(0.2)	6	(0.2)
Nitrendipine	0		6	(0.3)	6	(0.2)
Benidipine Hydrochloride	2	(0.1)	3	(0.2)	5	(0.1)
Cilnidipine	3	(0.2)	2	(0.1)	5	(0.1)
Manidipine	3	(0.2)	2	(0.1)	5	(0.1)
Levamlodipine Besilate	2	(0.1)	1	(0.1)	3	(0.1)
Manidipine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Amlodipine Maleate	0		2	(0.1)	2	(0.1)
Barnidipine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Nicardipine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Camsilate	0		1	(0.1)	1	(0.0)
Efonidipine Hydrochloride	0		1	(0.1)	1	(0.0)
Nimodipine	0		1	(0.1)	1	(0.0)
S Amlodipine Nicotinate	1	(0.1)	0		1	(0.0)
Multiple Atc, 0	435	(23.1)	378	(20.1)	813	(21.6)
Multivitamins, Plain	65	(3.5)	55	(2.9)	120	(3.2)
Ascorbic Acid	40	(2.1)	35	(1.9)	75	(2.0)
Sildenafil Citrate	21	(1.1)	10	(0.5)	31	(0.8)
Fluticasone	20	(1.1)	10	(0.5)	30	(0.8)
Sildenafil	16	(0.8)	14	(0.8)	30	(0.8)
Mecobalamin	17	(0.9)	10	(0.5)	27	(0.7)
Hyaluronate Sodium	15	(0.8)	9	(0.5)	24	(0.6)
Zinc	13	(0.7)	11	(0.6)	24	(0.6)
Iron	12	(0.6)	10	(0.5)	22	(0.6)
Potassium	11	(0.6)	11	(0.6)	22	(0.6)
Curcuma Longa Rhizome	10	(0.5)	11	(0.6)	21	(0.6)
Vitamins Nos	13	(0.7)	8	(0.4)	21	(0.6)
Cinnamomum Verum	6	(0.3)	13	(0.7)	19	(0.5)
Tocopherol	12	(0.6)	7	(0.4)	19	(0.5)
Budesonide	8	(0.4)	10	(0.5)	18	(0.5)
Heparinoid	5	(0.3)	8	(0.4)	13	(0.3)
Silybum Marianum	9	(0.5)	3	(0.2)	12	(0.3)
Beclometasone Dipropionate	4	(0.2)	7	(0.4)	11	(0.3)
Docusate Sodium	1	(0.1)	10	(0.5)	11	(0.3)
Minerals Nos; Vitamins Nos	4	(0.2)	7	(0.4)	11	(0.3)
Mometasone Furoate	6	(0.3)	5	(0.3)	11	(0.3)
Vaccinium Macrocarpon	5	(0.3)	6	(0.3)	11	(0.3)
Formoterol	4	(0.2)	6	(0.3)	10	(0.3)
Clobetasol Propionate	7	(0.4)	2	(0.1)	9	(0.2)
Fluconazole	7	(0.4)	2	(0.1)	9	(0.2)
Glucosamine	4	(0.2)	5	(0.3)	9	(0.2)
Glycopyrronium Bromide	1	(0.1)	8	(0.4)	9	(0.2)
Glycyrrhiza Spp. Root; Paeonia Lactiflora Root	6	(0.3)	3	(0.2)	9	(0.2)
Hydrocortisone	4	(0.2)	5	(0.3)	9	(0.2)
Other Respiratory System Products	5	(0.3)	4	(0.2)	9	(0.2)
Pyridoxine Hydrochloride	5	(0.3)	4	(0.2)	9	(0.2)
Ciclesonide	2	(0.1)	6	(0.3)	8	(0.2)
Aciclovir	3	(0.2)	4	(0.2)	7	(0.2)
Bepotastine Besilate	7	(0.4)	0		7	(0.2)
Betamethasone Dipropionate	7	(0.4)	0		7	(0.2)
Brimonidine Tartrate	3	(0.2)	4	(0.2)	7	(0.2)
Clotrimazole	5	(0.3)	2	(0.1)	7	(0.2)
Fluticasone Furoate	2	(0.1)	5	(0.3)	7	(0.2)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Hydrocortisone Butyrate	6	(0.3)	1	(0.1)	7	(0.2)
Ketoconazole	5	(0.3)	2	(0.1)	7	(0.2)
Nystatin	4	(0.2)	3	(0.2)	7	(0.2)
Ascorbic Acid; Betacarotene; Cupric Oxide; Tocopheryl Acetate; Zinc Oxide	2	(0.1)	4	(0.2)	6	(0.2)
Calcifediol	5	(0.3)	1	(0.1)	6	(0.2)
Clobetasol	5	(0.3)	1	(0.1)	6	(0.2)
Doxepin	2	(0.1)	4	(0.2)	6	(0.2)
Lidocaine	3	(0.2)	3	(0.2)	6	(0.2)
Plantago Ovata	3	(0.2)	3	(0.2)	6	(0.2)
Salmeterol	3	(0.2)	3	(0.2)	6	(0.2)
Triamcinolone	3	(0.2)	3	(0.2)	6	(0.2)
Urea	2	(0.1)	4	(0.2)	6	(0.2)
Vitamin B12 Nos	3	(0.2)	3	(0.2)	6	(0.2)
Azelastine	1	(0.1)	4	(0.2)	5	(0.1)
Krill Oil	2	(0.1)	3	(0.2)	5	(0.1)
Lamotrigine	2	(0.1)	3	(0.2)	5	(0.1)
Linum Usitatissimum Seed Oil	3	(0.2)	2	(0.1)	5	(0.1)
Meclozine	3	(0.2)	2	(0.1)	5	(0.1)
Nicotinamide	4	(0.2)	1	(0.1)	5	(0.1)
Prazosin	2	(0.1)	3	(0.2)	5	(0.1)
Probiotics [Umbrella Term]	3	(0.2)	2	(0.1)	5	(0.1)
Tacrolimus	2	(0.1)	3	(0.2)	5	(0.1)
Allium Sativum	0		4	(0.2)	4	(0.1)
Betamethasone	3	(0.2)	1	(0.1)	4	(0.1)
Betamethasone Butyrate Propionate	3	(0.2)	1	(0.1)	4	(0.1)
Calcium; Vitamin D Nos	3	(0.2)	1	(0.1)	4	(0.1)
Chondroitin Sulfate Sodium	1	(0.1)	3	(0.2)	4	(0.1)
Cod-Liver Oil	4	(0.2)	0		4	(0.1)
Docusate	2	(0.1)	2	(0.1)	4	(0.1)
Formoterol Fumarate Dihydrate	4	(0.2)	0		4	(0.1)
Ginkgo Biloba	1	(0.1)	3	(0.2)	4	(0.1)
Hydroxychloroquine	3	(0.2)	1	(0.1)	4	(0.1)
Hypromellose	3	(0.2)	1	(0.1)	4	(0.1)
Magnesium Chloride	1	(0.1)	3	(0.2)	4	(0.1)
Methylprednisolone	1	(0.1)	3	(0.2)	4	(0.1)
Prednisone	3	(0.2)	1	(0.1)	4	(0.1)
Pyridoxine	3	(0.2)	1	(0.1)	4	(0.1)
Riboflavin	3	(0.2)	1	(0.1)	4	(0.1)
Terbinafine	2	(0.1)	2	(0.1)	4	(0.1)
Terbutaline Sulfate	2	(0.1)	2	(0.1)	4	(0.1)
Triamcinolone Acetonide	2	(0.1)	2	(0.1)	4	(0.1)
Azelastine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Betamethasone Valerate	1	(0.1)	2	(0.1)	3	(0.1)
Borneol; Panax Notoginseng Root With Rhizome; Salvia Miltiorrhiza Root With Rhizome	1	(0.1)	2	(0.1)	3	(0.1)
Brimonidine	1	(0.1)	2	(0.1)	3	(0.1)
Calcium Chloride	1	(0.1)	2	(0.1)	3	(0.1)
Carteolol Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Chondroitin; Glucosamine	1	(0.1)	2	(0.1)	3	(0.1)
Dexamethasone	0		3	(0.2)	3	(0.1)
Fluorometholone	3	(0.2)	0		3	(0.1)
Formoterol Fumarate	0		3	(0.2)	3	(0.1)
Gentamicin Sulfate	1	(0.1)	2	(0.1)	3	(0.1)
Ginkgo Biloba Extract	1	(0.1)	2	(0.1)	3	(0.1)
Glycine Max Seed Oil; Persea Americana Oil	3	(0.2)	0		3	(0.1)
Hydroxocobalamin	3	(0.2)	0		3	(0.1)
Ketotifen Fumarate	1	(0.1)	2	(0.1)	3	(0.1)
Levosalbutamol	2	(0.1)	1	(0.1)	3	(0.1)
Magnesium Aspartate; Potassium Aspartate	1	(0.1)	2	(0.1)	3	(0.1)
Magnesium Citrate	1	(0.1)	2	(0.1)	3	(0.1)
Meclozine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Methadone	3	(0.2)	0		3	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Methylsulfonylmethane	1	(0.1)	2	(0.1)	3	(0.1)
Nimesulide	2	(0.1)	1	(0.1)	3	(0.1)
Potassium Citrate	2	(0.1)	1	(0.1)	3	(0.1)
Povidone-Iodine	0		3	(0.2)	3	(0.1)
Quinine Hydrochloride	3	(0.2)	0		3	(0.1)
Sucralfate	1	(0.1)	2	(0.1)	3	(0.1)
Sulfasalazine	2	(0.1)	1	(0.1)	3	(0.1)
Terbinafine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Thyroid	1	(0.1)	2	(0.1)	3	(0.1)
Tranilast	2	(0.1)	1	(0.1)	3	(0.1)
Vardenafil Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Achyranthes Bidentata Root; Aconitum Spp. Processed Root; Alisma Orientale Tuber; Cinnamomum Cassia Bark; Cornus Officinalis Fruit; Dioscorea Spp. Rhizome; Paeonia X Suffruticosa Root Bark; Plantago Asiatica	2	(0.1)	0		2	(0.1)
Angelica Acutiloba Root; Astragalus Spp. Root; Atractylodes Lancea Rhizome; Bupleurum Falcatum Root; Cimicifuga Spp. Rhizome; Citrus Aurantium Peel; Glycyrrhiza Spp. Root; Panax Ginseng Root; Zingiber Officin	1	(0.1)	1	(0.1)	2	(0.1)
Angelica Acutiloba Root; Bupleurum Falcatum Root; Cimicifuga Spp. Rhizome; Glycyrrhiza Spp. Root; Rheum Spp. Rhizome; Scutellaria Baicalensis Root	0		2	(0.1)	2	(0.1)
Beclometasone	1	(0.1)	1	(0.1)	2	(0.1)
Berberine	2	(0.1)	0		2	(0.1)
Betamethasone Sodium Phosphate	1	(0.1)	1	(0.1)	2	(0.1)
Botulinum Toxin Type A	0		2	(0.1)	2	(0.1)
Bupivacaine	0		2	(0.1)	2	(0.1)
Caffeine	2	(0.1)	0		2	(0.1)
Cannabidiol	2	(0.1)	0		2	(0.1)
Cannabis Sativa	1	(0.1)	1	(0.1)	2	(0.1)
Carbasalate Calcium	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine Maleate	0		2	(0.1)	2	(0.1)
Chondroitin	2	(0.1)	0		2	(0.1)
Chondroitin Sulfate; Glucosamine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Ciprofloxacin	1	(0.1)	1	(0.1)	2	(0.1)
Clomipramine	1	(0.1)	1	(0.1)	2	(0.1)
Cocos Nucifera Oil	2	(0.1)	0		2	(0.1)
Cortisone	0		2	(0.1)	2	(0.1)
Cyamopsis Tetragonoloba Gum	2	(0.1)	0		2	(0.1)
Dupilumab	1	(0.1)	1	(0.1)	2	(0.1)
Fenoterol	2	(0.1)	0		2	(0.1)
Fluocinonide	1	(0.1)	1	(0.1)	2	(0.1)
Glucosamine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Glycine Max	1	(0.1)	1	(0.1)	2	(0.1)
Glycopyrronium	1	(0.1)	1	(0.1)	2	(0.1)
Guaiazulene	1	(0.1)	1	(0.1)	2	(0.1)
Hydrocortisone Acetate	0		2	(0.1)	2	(0.1)
Hydroxycarbamide	2	(0.1)	0		2	(0.1)
Lactobacillus Acidophilus	0		2	(0.1)	2	(0.1)
Lithium	0		2	(0.1)	2	(0.1)
Lysine	2	(0.1)	0		2	(0.1)
Macrogol	0		2	(0.1)	2	(0.1)
Magnesium Lactate; Pyridoxine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Maxacalcitol	1	(0.1)	1	(0.1)	2	(0.1)
Metoclopramide Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Metronidazole	1	(0.1)	1	(0.1)	2	(0.1)
Mometasone	1	(0.1)	1	(0.1)	2	(0.1)
Morphine	0		2	(0.1)	2	(0.1)
Mucopolysaccharide Polysulfuric Acid Ester	1	(0.1)	1	(0.1)	2	(0.1)
Naftopidil	1	(0.1)	1	(0.1)	2	(0.1)
Naloxone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Nystatin; Triamcinolone	0		2	(0.1)	2	(0.1)
Oenothera Biennis Oil	1	(0.1)	1	(0.1)	2	(0.1)
Ornidazole	0		2	(0.1)	2	(0.1)
Pantothenic Acid	2	(0.1)	0		2	(0.1)
Persea Americana	1	(0.1)	1	(0.1)	2	(0.1)
Potassium Aspartate	0		2	(0.1)	2	(0.1)
Potassium Iodide	0		2	(0.1)	2	(0.1)
Prazosin Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Prednisolone Acetate	1	(0.1)	1	(0.1)	2	(0.1)
Procaterol Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Prunus Cerasus	1	(0.1)	1	(0.1)	2	(0.1)
Quercetin	1	(0.1)	1	(0.1)	2	(0.1)
Retinol	2	(0.1)	0		2	(0.1)
Selenium	1	(0.1)	1	(0.1)	2	(0.1)
Sitosterol	0		2	(0.1)	2	(0.1)
Sodium Bicarbonate; Sodium Chloride	1	(0.1)	1	(0.1)	2	(0.1)
Sodium Gualenate Hydrate	1	(0.1)	1	(0.1)	2	(0.1)
Taurine	1	(0.1)	1	(0.1)	2	(0.1)
Tretinoin	1	(0.1)	1	(0.1)	2	(0.1)
Trospium	2	(0.1)	0		2	(0.1)
Trospium Chloride	2	(0.1)	0		2	(0.1)
Vaccinium Myrtillus	2	(0.1)	0		2	(0.1)
Abelmoschus Manihot Flower	0		1	(0.1)	1	(0.0)
Acetazolamide	0		1	(0.1)	1	(0.0)
Acetylcarnitine	1	(0.1)	0		1	(0.0)
Acetylcarnitine Hydrochloride	0		1	(0.1)	1	(0.0)
Acetylcysteine	0		1	(0.1)	1	(0.0)
Aconitum Spp. Processed Root; Alisma Orientale Tuber; Cinnamomum Cassia Bark; Cornus Officinalis Fruit; Dioscorea Spp. Rhizome; Paeonia X Suffruticosa Root Bark; Poria Cocos Sclerotium; Rehmannia Glutinosa R	0		1	(0.1)	1	(0.0)
Aconitum Spp. Processed Root; Atractylodes Lancea Rhizome; Cinnamomum Cassia Bark; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	0		1	(0.1)	1	(0.0)
Ademetionine	1	(0.1)	0		1	(0.0)
Alclometasone Dipropionate	0		1	(0.1)	1	(0.0)
Alisma Orientale Tuber; Angelica Acutiloba Root; Atractylodes Lancea Rhizome; Cnidium Officinale Rhizome; Paeonia Lactiflora Root; Poria Cocos Sclerotium	1	(0.1)	0		1	(0.0)
Alisma Orientale Tuber; Atractylodes Lancea Rhizome; Cinnamomum Cassia Bark; Polyporus Umbellatus Sclerotium; Poria Cocos Sclerotium	1	(0.1)	0		1	(0.0)
All Other Therapeutic Products	1	(0.1)	0		1	(0.0)
Allium Sativum Extract	1	(0.1)	0		1	(0.0)
Allium Sativum Oil	0		1	(0.1)	1	(0.0)
Althaea Officinalis Extract; Arctium Lappa Extract; Echinacea Angustifolia Extract; Eucalyptus Globulus Extract; Hydrastis Canadensis Extract; Petroselinum Crispum Extract; Trigonella Foenum-Graecum Extract	0		1	(0.1)	1	(0.0)
Ambroxol	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Atractylodes Lancea Rhizome; Bupleurum Falcatum Root; Gardenia Jasminoides Fruit; Glycyrrhiza Spp. Root; Mentha Canadensis Herb; Paeonia Lactiflora Root; Paeonia X Suffruticosa Root	0		1	(0.1)	1	(0.0)
Angelica Sinensis; Ligusticum Chuanxiong	1	(0.1)	0		1	(0.0)
Artemisia Argyi Leaf	0		1	(0.1)	1	(0.0)
Asarum Spp. Root; Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root;	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Paeonia Lactiflora Root; Pinellia Ternata Tuber; Schisandra Chinensis Fruit; Zingiber Officinale Rhizome						
Ascorbic Acid; Bioflavonoids Nos; Choline Bitartrate; Dl-Methionine; Hydroxocobalamin; Inositol; Nicotinamide; Panthenol; Pyridoxine; Riboflavin; Thiamine	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Colecalciferol; Herbal Nos; Retinol Palmitate; Sambucus Nigra; Sodium; Tocopheryl Acetate; Zinc Citrate	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Ferrous Fumarate	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Ferrous Sulfate	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Vaccinium Macrocarpon	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Zinc	0		1	(0.1)	1	(0.0)
Azithromycin	1	(0.1)	0		1	(0.0)
Benzyl Nicotinate	1	(0.1)	0		1	(0.0)
Berberine Hydrochloride; Rheum Spp. Root With Rhizome; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Betamethasone Valerate; Gentamicin Sulfate	0		1	(0.1)	1	(0.0)
Borneol; Boswellia Sacra Resin; Centipede; Cicada Slough; Dalbergia Odorifera; Eupolyphaga Steleophaga; Leech; Mesobuthus Martensii; Paeonia Spp. Root; Panax Ginseng Root; Santalum Album Heartwood; Ziziphus Juju	1	(0.1)	0		1	(0.0)
Boswellia Serrata	0		1	(0.1)	1	(0.0)
Boswellia Serrata; Bromelains; Curcuma Longa Rhizome; Magnesium Citrate; Piperine; Quercetin Dihydrate	1	(0.1)	0		1	(0.0)
Buprenorphine	1	(0.1)	0		1	(0.0)
Cabergoline	0		1	(0.1)	1	(0.0)
Calcium; Magnesium; Vitamin D Nos	0		1	(0.1)	1	(0.0)
Cannabis Sativa Fruit; Citrus Spp. Unripe Fruit; Magnolia Spp. Bark; Paeonia Lactiflora Root; Prunus Spp. Seed; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Carbomer	1	(0.1)	0		1	(0.0)
Carmellose Sodium	0		1	(0.1)	1	(0.0)
Carnosine	1	(0.1)	0		1	(0.0)
Carteolol	1	(0.1)	0		1	(0.0)
Centella Asiatica Extract	0		1	(0.1)	1	(0.0)
Chlorella Spp.; Plantago Ovata Seed Husk; Spirulina Spp.	0		1	(0.1)	1	(0.0)
Choline; Inositol	0		1	(0.1)	1	(0.0)
Chondroitin Sulfate; Glucosamine	1	(0.1)	0		1	(0.0)
Chromium	0		1	(0.1)	1	(0.0)
Cimicifuga Racemosa	0		1	(0.1)	1	(0.0)
Cimicifuga Racemosa Extract	1	(0.1)	0		1	(0.0)
Cinnamomum Cassia Bark; Cnidium Officinale Rhizome; Glycyrrhiza Spp. Root; Nuphar Japonica Rhizome; Quercus Spp. Bark; Rheum Spp. Rhizome; Syzygium Aromaticum Flower Bud	1	(0.1)	0		1	(0.0)
Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Pueraria Lobata Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	0		1	(0.1)	1	(0.0)
Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Prunus Spp. Seed	1	(0.1)	0		1	(0.0)
Clarithromycin	0		1	(0.1)	1	(0.0)
Clenbuterol Hydrochloride	1	(0.1)	0		1	(0.0)
Clindamycin	0		1	(0.1)	1	(0.0)
Clindamycin Phosphate	0		1	(0.1)	1	(0.0)
Clioquinol	1	(0.1)	0		1	(0.0)
Clobetasone Butyrate	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Clomipramine Hydrochloride	0		1	(0.1)	1	(0.0)
Collagen	1	(0.1)	0		1	(0.0)
Colostrum	0		1	(0.1)	1	(0.0)
Cromoglicate Sodium	0		1	(0.1)	1	(0.0)
Cromoglicic Acid	1	(0.1)	0		1	(0.0)
Curcuma Longa	1	(0.1)	0		1	(0.0)
Curcuma Longa Rhizome; Tamarindus Indica Seed	1	(0.1)	0		1	(0.0)
Curcuma Zedoaria; Laminaria Japonica	0		1	(0.1)	1	(0.0)
Cyclizine	1	(0.1)	0		1	(0.0)
Dexpanthenol	1	(0.1)	0		1	(0.0)
Dextran	0		1	(0.1)	1	(0.0)
Difluprednate	1	(0.1)	0		1	(0.0)
Dimenhydrinate	0		1	(0.1)	1	(0.0)
Dimetindene Maleate	0		1	(0.1)	1	(0.0)
Doxepin Hydrochloride	0		1	(0.1)	1	(0.0)
Doxylamine Succinate	0		1	(0.1)	1	(0.0)
Elastase	1	(0.1)	0		1	(0.0)
Etofenamate	1	(0.1)	0		1	(0.0)
Etretinate	1	(0.1)	0		1	(0.0)
Famciclovir	1	(0.1)	0		1	(0.0)
Fenoterol Hydrobromide	1	(0.1)	0		1	(0.0)
Ferric Hydroxide Polymaltose	1	(0.1)	0		1	(0.0)
Ferrous Sulfate; Vitamins Nos	1	(0.1)	0		1	(0.0)
Fexofenadine Hydrochloride; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Flunisolide	1	(0.1)	0		1	(0.0)
Fluocinolone Acetonide	0		1	(0.1)	1	(0.0)
Glycerol	0		1	(0.1)	1	(0.0)
Glycerol; Propylene Glycol	0		1	(0.1)	1	(0.0)
Glycine Max Seed Oil	0		1	(0.1)	1	(0.0)
Glycyrrhiza Glabra Root	1	(0.1)	0		1	(0.0)
Glycyrrhiza Spp. Root; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Gramicidin; Neomycin; Nystatin; Triamcinolone	1	(0.1)	0		1	(0.0)
Herbal Pollen Nos	1	(0.1)	0		1	(0.0)
Hydrocortisone; Oxytetracycline; Polymyxin B	1	(0.1)	0		1	(0.0)
Immunotherapy	1	(0.1)	0		1	(0.0)
Inositol	1	(0.1)	0		1	(0.0)
Iodine	0		1	(0.1)	1	(0.0)
Iron Polysaccharide Complex	1	(0.1)	0		1	(0.0)
Isoconazole	1	(0.1)	0		1	(0.0)
Lactobacillus Nos	1	(0.1)	0		1	(0.0)
Leuprorelin	0		1	(0.1)	1	(0.0)
Levofloxacin	1	(0.1)	0		1	(0.0)
Lidocaine Hydrochloride	1	(0.1)	0		1	(0.0)
Linum Usitatissimum Seed	1	(0.1)	0		1	(0.0)
Liver Extract	0		1	(0.1)	1	(0.0)
Macrocystis Pyrifera	1	(0.1)	0		1	(0.0)
Macrogol 400	1	(0.1)	0		1	(0.0)
Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Magnesium Phosphate	1	(0.1)	0		1	(0.0)
Matricaria Recutita	1	(0.1)	0		1	(0.0)
Mephenoxalone	0		1	(0.1)	1	(0.0)
Mepyramine Maleate	1	(0.1)	0		1	(0.0)
Methyl Salicylate	0		1	(0.1)	1	(0.0)
Methylcellulose	1	(0.1)	0		1	(0.0)
Metoclopramide	1	(0.1)	0		1	(0.0)
Miconazole	1	(0.1)	0		1	(0.0)
Monascus Purpureus	1	(0.1)	0		1	(0.0)
Moringa Oleifera	1	(0.1)	0		1	(0.0)
Moxifloxacin	0		1	(0.1)	1	(0.0)
Mupirocin	0		1	(0.1)	1	(0.0)
Muscle Relaxants	0		1	(0.1)	1	(0.0)
Naloxone	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Naloxone Hydrochloride; Tilidine Hydrochloride	1	(0.1)	0		1	(0.0)
Naphazoline Hydrochloride; Pheniramine Maleate	0		1	(0.1)	1	(0.0)
Neticonazole Hydrochloride	1	(0.1)	0		1	(0.0)
Nutrients Nos	0		1	(0.1)	1	(0.0)
Ononis Spinosa Root Extract; Orthosiphon Aristatus Leaf Extract; Solidago Virgaurea Herb Extract	1	(0.1)	0		1	(0.0)
Orphenadrine	1	(0.1)	0		1	(0.0)
Other Cardiac Preparations	0		1	(0.1)	1	(0.0)
Other Ophthalmologicals	0		1	(0.1)	1	(0.0)
Oxygen	1	(0.1)	0		1	(0.0)
Oxymetazoline Hydrochloride	0		1	(0.1)	1	(0.0)
Papain	0		1	(0.1)	1	(0.0)
Paraffin; Wool Fat	0		1	(0.1)	1	(0.0)
Pentosan Polysulfate Sodium	1	(0.1)	0		1	(0.0)
Phleum Pratense Pollen	1	(0.1)	0		1	(0.0)
Plantago Afra	1	(0.1)	0		1	(0.0)
Plantago Psyllium	1	(0.1)	0		1	(0.0)
Polaprezinc	1	(0.1)	0		1	(0.0)
Polyene Phosphatidylcholine	0		1	(0.1)	1	(0.0)
Polymyxin B	1	(0.1)	0		1	(0.0)
Potassium Citrate; Sodium Citrate Dihydrate	1	(0.1)	0		1	(0.0)
Povidone	1	(0.1)	0		1	(0.0)
Prasterone	1	(0.1)	0		1	(0.0)
Propylene Glycol	1	(0.1)	0		1	(0.0)
Prunus Africana Extract	1	(0.1)	0		1	(0.0)
Quinidine	1	(0.1)	0		1	(0.0)
Quinine Sulfate	0		1	(0.1)	1	(0.0)
Rhamnus Cathartica; Rhamnus Purshiana; Senna Spp.	1	(0.1)	0		1	(0.0)
Rhodiola Rosea	1	(0.1)	0		1	(0.0)
Rifaximin	1	(0.1)	0		1	(0.0)
Saccharated Iron Oxide	1	(0.1)	0		1	(0.0)
Salmeterol Xinafoate	0		1	(0.1)	1	(0.0)
Sambucus Nigra	0		1	(0.1)	1	(0.0)
Sea Water	0		1	(0.1)	1	(0.0)
Senna Alexandrina	1	(0.1)	0		1	(0.0)
Serenoa Repens	1	(0.1)	0		1	(0.0)
Serenoa Repens Extract; Urtica Dioica Extract	1	(0.1)	0		1	(0.0)
Serenoa Repens Fruit	1	(0.1)	0		1	(0.0)
Sertaconazole Nitrate	1	(0.1)	0		1	(0.0)
Sodium Alginate	0		1	(0.1)	1	(0.0)
Sodium Bicarbonate	1	(0.1)	0		1	(0.0)
Sodium Chloride	1	(0.1)	0		1	(0.0)
Sulfadiazine Silver	1	(0.1)	0		1	(0.0)
Sulfamethoxazole	0		1	(0.1)	1	(0.0)
Sulpiride	1	(0.1)	0		1	(0.0)
Tacrolimus Monohydrate	1	(0.1)	0		1	(0.0)
Tetracycline Hydrochloride	0		1	(0.1)	1	(0.0)
Thalidomide	0		1	(0.1)	1	(0.0)
Tolperisone Hydrochloride	1	(0.1)	0		1	(0.0)
Tribenoside	0		1	(0.1)	1	(0.0)
Trifolium Pratense	1	(0.1)	0		1	(0.0)
Trigonella Foenum-Graecum	1	(0.1)	0		1	(0.0)
Troxerutin	1	(0.1)	0		1	(0.0)
Vaccinium Myrtillus Extract	1	(0.1)	0		1	(0.0)
Vaccinium Spp.	0		1	(0.1)	1	(0.0)
Valproate Semisodium	1	(0.1)	0		1	(0.0)
Vitamin E Nos	1	(0.1)	0		1	(0.0)
Vitis Vinifera Seed	0		1	(0.1)	1	(0.0)
Zinc Sulfate	1	(0.1)	0		1	(0.0)
Zingiber Officinale Rhizome	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Glucagon-Like Peptide-1 (Glp-1) Analogues, A10bj	400	(21.3)	400	(21.3)	800	(21.3)
Dulaglutide	158	(8.4)	146	(7.8)	304	(8.1)
Semaglutide	143	(7.6)	158	(8.4)	301	(8.0)
Liraglutide	86	(4.6)	87	(4.6)	173	(4.6)
Exenatide	12	(0.6)	7	(0.4)	19	(0.5)
Lixisenatide	1	(0.1)	2	(0.1)	3	(0.1)
Proton Pump Inhibitors, A02bc	309	(16.4)	289	(15.4)	598	(15.9)
Omeprazole	115	(6.1)	108	(5.8)	223	(5.9)
Pantoprazole Sodium Sesquihydrate	74	(3.9)	60	(3.2)	134	(3.6)
Pantoprazole	34	(1.8)	35	(1.9)	69	(1.8)
Lansoprazole	24	(1.3)	26	(1.4)	50	(1.3)
Esomeprazole Magnesium	24	(1.3)	17	(0.9)	41	(1.1)
Esomeprazole	15	(0.8)	13	(0.7)	28	(0.8)
Vonoprazan Fumarate	5	(0.3)	11	(0.6)	16	(0.4)
Rabeprazole Sodium	6	(0.3)	9	(0.5)	15	(0.4)
Dexlansoprazole	8	(0.4)	4	(0.2)	12	(0.3)
Rabeprazole	2	(0.1)	6	(0.3)	8	(0.2)
Pantoprazole Magnesium	1	(0.1)	1	(0.1)	2	(0.1)
Tegoprazan	2	(0.1)	0		2	(0.1)
Esomeprazole Magnesium Trihydrate	0		1	(0.1)	1	(0.0)
Pantoprazole Hemimagnesium Hydrate	0		1	(0.1)	1	(0.0)
Insulin (Human), A10ab01	266	(14.2)	262	(13.9)	528	(14.1)
Insulin Aspart	163	(8.7)	147	(7.8)	310	(8.2)
Insulin Lispro	101	(5.4)	113	(6.0)	214	(5.7)
Insulin Human	2	(0.1)	2	(0.1)	4	(0.1)
Thiazides, Plain, C03aa	245	(13.0)	185	(9.8)	430	(11.4)
Hydrochlorothiazide	239	(12.7)	181	(9.6)	420	(11.2)
Bendroflumethiazide	4	(0.2)	4	(0.2)	8	(0.2)
Trichlormethiazide	2	(0.1)	0		2	(0.1)
Thyroid Hormones, H03aa	190	(10.1)	214	(11.4)	404	(10.8)
Levothyroxine Sodium	116	(6.2)	134	(7.1)	250	(6.7)
Levothyroxine	72	(3.8)	80	(4.3)	152	(4.0)
Levothyroxine; Liothyronine	2	(0.1)	1	(0.1)	3	(0.1)
Liothyronine Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Liothyronine	0		1	(0.1)	1	(0.0)
Vitamin D And Analogues, A11cc	213	(11.3)	180	(9.6)	393	(10.5)
Colecalciferol	127	(6.8)	97	(5.2)	224	(6.0)
Vitamin D Nos	75	(4.0)	67	(3.6)	142	(3.8)
Ergocalciferol	8	(0.4)	9	(0.5)	17	(0.5)
Colecalciferol-Cholesterin	3	(0.2)	4	(0.2)	7	(0.2)
Alfacalcidol	1	(0.1)	2	(0.1)	3	(0.1)
Eldecalcitol	1	(0.1)	2	(0.1)	3	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Lipid Modifying Agents, C10ax	189	(10.1)	173	(9.2)	362	(9.6)
Ezetimibe	109	(5.8)	82	(4.4)	191	(5.1)
Fish Oil	47	(2.5)	51	(2.7)	98	(2.6)
Eicosapentaenoic Acid Ethyl Ester	21	(1.1)	23	(1.2)	44	(1.2)
Omega-3-Acid Ethyl Ester	10	(0.5)	9	(0.5)	19	(0.5)
Evolocumab	2	(0.1)	6	(0.3)	8	(0.2)
Omega-3 Fatty Acids	3	(0.2)	5	(0.3)	8	(0.2)
Eicosapentaenoic Acid	3	(0.2)	0		3	(0.1)
Omega-3 Triglycerides	1	(0.1)	1	(0.1)	2	(0.1)
Alirocumab	1	(0.1)	0		1	(0.0)
Colecalciferol; Fish Oil	0		1	(0.1)	1	(0.0)
Docosahexaenoic Acid; Eicosapentaenoic Acid; Fish Oil	1	(0.1)	0		1	(0.0)
Fish Oil; Krill Oil	0		1	(0.1)	1	(0.0)
Fish Oil; Omega-3 Fatty Acids	1	(0.1)	0		1	(0.0)
Fish Oil; Tocopherol	0		1	(0.1)	1	(0.0)
Linolenic Acid	1	(0.1)	0		1	(0.0)
Omega 9 Fatty Acids	0		1	(0.1)	1	(0.0)
Omega 9 Fatty Acids; Omega-3 Fatty Acids; Omega-6 Fatty Acids	0		1	(0.1)	1	(0.0)
Probucol	1	(0.1)	0		1	(0.0)
Fibrates, C10ab	148	(7.9)	171	(9.1)	319	(8.5)
Fenofibrate	105	(5.6)	126	(6.7)	231	(6.2)
Bezafibrate	22	(1.2)	19	(1.0)	41	(1.1)
Gemfibrozil	10	(0.5)	7	(0.4)	17	(0.5)
Pemafibrate	5	(0.3)	12	(0.6)	17	(0.5)
Ciprofibrate	4	(0.2)	4	(0.2)	8	(0.2)
Fenofibric Acid	1	(0.1)	3	(0.2)	4	(0.1)
Choline Fenofibrate	1	(0.1)	0		1	(0.0)
Sulfonamides, Plain, C03ba	133	(7.1)	140	(7.5)	273	(7.3)
Indapamide	124	(6.6)	128	(6.8)	252	(6.7)
Chlortalidone	8	(0.4)	11	(0.6)	19	(0.5)
Clopamide	2	(0.1)	1	(0.1)	3	(0.1)
Metolazone	1	(0.1)	0		1	(0.0)
Other Antidepressants, N06ax	100	(5.3)	115	(6.1)	215	(5.7)
Trazodone	16	(0.8)	27	(1.4)	43	(1.1)
Duloxetine	16	(0.8)	22	(1.2)	38	(1.0)
Duloxetine Hydrochloride	14	(0.7)	18	(1.0)	32	(0.8)
Venlafaxine Hydrochloride	15	(0.8)	12	(0.6)	27	(0.7)
Venlafaxine	11	(0.6)	15	(0.8)	26	(0.7)
Mirtazapine	14	(0.7)	9	(0.5)	23	(0.6)
Bupropion	7	(0.4)	11	(0.6)	18	(0.5)
Bupropion Hydrochloride	11	(0.6)	6	(0.3)	17	(0.5)
Trazodone Hydrochloride	5	(0.3)	5	(0.3)	10	(0.3)
Desvenlafaxine	0		2	(0.1)	2	(0.1)
Tianeptine Sodium	2	(0.1)	0		2	(0.1)
Vortioxetine Hydrobromide	1	(0.1)	1	(0.1)	2	(0.1)
Agomelatine Urea	0		1	(0.1)	1	(0.0)
Desvenlafaxine Succinate Monohydrate	0		1	(0.1)	1	(0.0)
Vilazodone Hydrochloride	1	(0.1)	0		1	(0.0)
Vortioxetine	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Selective Serotonin Reuptake Inhibitors, N06ab	123	(6.5)	88	(4.7)	211	(5.6)
Escitalopram Oxalate	25	(1.3)	14	(0.8)	39	(1.0)
Citalopram	19	(1.0)	14	(0.8)	33	(0.9)
Escitalopram	20	(1.1)	13	(0.7)	33	(0.9)
Sertraline	9	(0.5)	13	(0.7)	22	(0.6)
Fluoxetine	13	(0.7)	6	(0.3)	19	(0.5)
Sertraline Hydrochloride	14	(0.7)	3	(0.2)	17	(0.5)
Fluoxetine Hydrochloride	8	(0.4)	7	(0.4)	15	(0.4)
Paroxetine	8	(0.4)	4	(0.2)	12	(0.3)
Citalopram Hydrobromide	2	(0.1)	9	(0.5)	11	(0.3)
Paroxetine Hydrochloride	5	(0.3)	3	(0.2)	8	(0.2)
Fluvoxamine Maleate	0		2	(0.1)	2	(0.1)
Preparations Inhibiting Uric Acid Production, M04aa	86	(4.6)	111	(5.9)	197	(5.2)
Allopurinol	70	(3.7)	96	(5.1)	166	(4.4)
Febuxostat	14	(0.7)	15	(0.8)	29	(0.8)
Topiroxostat	2	(0.1)	0		2	(0.1)
Thiazolidinediones, A10bg	97	(5.2)	80	(4.3)	177	(4.7)
Pioglitazone	54	(2.9)	54	(2.9)	108	(2.9)
Pioglitazone Hydrochloride	42	(2.2)	26	(1.4)	68	(1.8)
Lobeglitazone Sulfate	1	(0.1)	0		1	(0.0)
Gabapentin, N03ax12	79	(4.2)	83	(4.4)	162	(4.3)
Gabapentin	79	(4.2)	83	(4.4)	162	(4.3)
Propionic Acid Derivatives, M01ae	69	(3.7)	85	(4.5)	154	(4.1)
Ibuprofen	38	(2.0)	43	(2.3)	81	(2.2)
Naproxen	10	(0.5)	13	(0.7)	23	(0.6)
Loxoprofen Sodium Dihydrate	10	(0.5)	11	(0.6)	21	(0.6)
Naproxen Sodium	5	(0.3)	9	(0.5)	14	(0.4)
Loxoprofen Sodium	3	(0.2)	4	(0.2)	7	(0.2)
Ketoprofen	2	(0.1)	3	(0.2)	5	(0.1)
Flurbiprofen	1	(0.1)	1	(0.1)	2	(0.1)
Apronal; Caffeine; Ibuprofen	1	(0.1)	0		1	(0.0)
Apronal; Caffeine; Ibuprofen; Magnesium Oxide	1	(0.1)	0		1	(0.0)
Dexibuprofen	0		1	(0.1)	1	(0.0)
Dexketoprofen	0		1	(0.1)	1	(0.0)
Dexketoprofen Trometamol	1	(0.1)	0		1	(0.0)
Esomeprazole; Naproxen	1	(0.1)	0		1	(0.0)
Ibuprofen Lysinate	0		1	(0.1)	1	(0.0)
Ibuprofen Sodium	1	(0.1)	0		1	(0.0)
Ibuprofen; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Pranoprofen	1	(0.1)	0		1	(0.0)
Sulfonamides, Plain, C03ca	67	(3.6)	80	(4.3)	147	(3.9)
Furosemide	49	(2.6)	54	(2.9)	103	(2.7)
Torasemide	14	(0.7)	23	(1.2)	37	(1.0)
Bumetanide	2	(0.1)	2	(0.1)	4	(0.1)
Azosemide	1	(0.1)	1	(0.1)	2	(0.1)
Furosemide; Sodium Chloride	1	(0.1)	0		1	(0.0)
Alpha-Adrenoreceptor Antagonists, G04ca	70	(3.7)	76	(4.0)	146	(3.9)
Tamsulosin	22	(1.2)	35	(1.9)	57	(1.5)
Tamsulosin Hydrochloride	26	(1.4)	24	(1.3)	50	(1.3)
Silodosin	7	(0.4)	6	(0.3)	13	(0.3)
Alfuzosin	7	(0.4)	4	(0.2)	11	(0.3)
Alfuzosin Hydrochloride	6	(0.3)	2	(0.1)	8	(0.2)
Terazosin	3	(0.2)	3	(0.2)	6	(0.2)
Terazosin Hydrochloride	0		2	(0.1)	2	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamin B12 (Cyanocobalamin And Analogues), B03ba	76	(4.0)	65	(3.5)	141	(3.8)
Cyanocobalamin	68	(3.6)	57	(3.0)	125	(3.3)
Cyanocobalamin-Tannin Complex	1	(0.1)	4	(0.2)	5	(0.1)
Cyanocobalamin; Pyridoxine Hydrochloride; Thiamine Hydrochloride	3	(0.2)	1	(0.1)	4	(0.1)
Cyanocobalamin; Pyridoxine; Thiamine	2	(0.1)	1	(0.1)	3	(0.1)
Cyanocobalamin; Folic Acid	1	(0.1)	0		1	(0.0)
Cyanocobalamin; Folic Acid; Pyridoxine	0		1	(0.1)	1	(0.0)
Folic Acid; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Levomefolic Acid; Mecobalamin; Pyridoxine	1	(0.1)	0		1	(0.0)
Alpha Glucosidase Inhibitors, A10bf	65	(3.5)	70	(3.7)	135	(3.6)
Acarbose	36	(1.9)	38	(2.0)	74	(2.0)
Voglibose	16	(0.8)	21	(1.1)	37	(1.0)
Miglitol	13	(0.7)	11	(0.6)	24	(0.6)
Alpha And Beta Blocking Agents, C07ag	63	(3.4)	65	(3.5)	128	(3.4)
Carvedilol	62	(3.3)	63	(3.4)	125	(3.3)
Arotinolol Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Labetalol	0		1	(0.1)	1	(0.0)
Anilides, N02be	55	(2.9)	65	(3.5)	120	(3.2)
Paracetamol	52	(2.8)	58	(3.1)	110	(2.9)
Acetylsalicylic Acid; Caffeine; Paracetamol	4	(0.2)	1	(0.1)	5	(0.1)
Caffeine; Paracetamol	0		4	(0.2)	4	(0.1)
Apronal; Caffeine; Paracetamol; Propyphenazone	0		1	(0.1)	1	(0.0)
Butalbital; Caffeine; Codeine Phosphate; Paracetamol	0		1	(0.1)	1	(0.0)
Butalbital; Caffeine; Paracetamol	0		1	(0.1)	1	(0.0)
Ibuprofen; Paracetamol	1	(0.1)	0		1	(0.0)
Selective Beta-2-Adrenoreceptor Agonists, R03ac	56	(3.0)	58	(3.1)	114	(3.0)
Salbutamol	38	(2.0)	36	(1.9)	74	(2.0)
Salbutamol Sulfate	16	(0.8)	17	(0.9)	33	(0.9)
Vilanterol	5	(0.3)	1	(0.1)	6	(0.2)
Indacaterol	1	(0.1)	1	(0.1)	2	(0.1)
Indacaterol Maleate	0		2	(0.1)	2	(0.1)
Ipratropium Bromide; Salbutamol Sulfate	0		1	(0.1)	1	(0.0)
Olodaterol Hydrochloride	1	(0.1)	0		1	(0.0)
Vilanterol Trifenatate	0		1	(0.1)	1	(0.0)
Other Antihistamines For Systemic Use, R06ax	54	(2.9)	57	(3.0)	111	(3.0)
Loratadine	26	(1.4)	27	(1.4)	53	(1.4)
Fexofenadine Hydrochloride	7	(0.4)	12	(0.6)	19	(0.5)
Desloratadine	6	(0.3)	4	(0.2)	10	(0.3)
Epinastine Hydrochloride	2	(0.1)	6	(0.3)	8	(0.2)
Bilastine	4	(0.2)	3	(0.2)	7	(0.2)
Olopatadine Hydrochloride	3	(0.2)	3	(0.2)	6	(0.2)
Fexofenadine	2	(0.1)	2	(0.1)	4	(0.1)
Rupatadine Fumarate	3	(0.2)	1	(0.1)	4	(0.1)
Ebastine	2	(0.1)	0		2	(0.1)
Epinastine	1	(0.1)	0		1	(0.0)
Aldosterone Antagonists, C03da	45	(2.4)	46	(2.5)	91	(2.4)
Spironolactone	39	(2.1)	38	(2.0)	77	(2.0)
Eplerenone	6	(0.3)	8	(0.4)	14	(0.4)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Calcium, A12aa	52	(2.8)	38	(2.0)	90	(2.4)
Calcium	30	(1.6)	22	(1.2)	52	(1.4)
Calcium Carbonate	19	(1.0)	12	(0.6)	31	(0.8)
Calcium Citrate	2	(0.1)	2	(0.1)	4	(0.1)
Ascorbic Acid; Calcium Carbonate; Colecalciferol; Pyridoxine Hydrochloride	1	(0.1)	0		1	(0.0)
Calcium Carbonate; Magnesium Carbonate	0		1	(0.1)	1	(0.0)
Calcium Carbonate; Vitamin D Nos	0		1	(0.1)	1	(0.0)
Direct Factor Xa Inhibitors, B01af	47	(2.5)	41	(2.2)	88	(2.3)
Apixaban	20	(1.1)	23	(1.2)	43	(1.1)
Rivaroxaban	22	(1.2)	15	(0.8)	37	(1.0)
Edoxaban	3	(0.2)	1	(0.1)	4	(0.1)
Edoxaban Tosilate	2	(0.1)	2	(0.1)	4	(0.1)
Prostaglandin Analogues, S01ee	42	(2.2)	41	(2.2)	83	(2.2)
Latanoprost	24	(1.3)	26	(1.4)	50	(1.3)
Bimatoprost	6	(0.3)	8	(0.4)	14	(0.4)
Travoprost	5	(0.3)	5	(0.3)	10	(0.3)
Tafluprost	5	(0.3)	1	(0.1)	6	(0.2)
Latanoprostene Bunod	2	(0.1)	0		2	(0.1)
Latanoprost; Netarsudil Mesilate	0		1	(0.1)	1	(0.0)
Benzodiazepine Derivatives, N05ba	37	(2.0)	44	(2.3)	81	(2.2)
Alprazolam	19	(1.0)	14	(0.8)	33	(0.9)
Lorazepam	8	(0.4)	14	(0.8)	22	(0.6)
Diazepam	3	(0.2)	5	(0.3)	8	(0.2)
Etizolam	2	(0.1)	3	(0.2)	5	(0.1)
Oxazepam	1	(0.1)	4	(0.2)	5	(0.1)
Bromazepam	2	(0.1)	2	(0.1)	4	(0.1)
Clotiazepam	0		2	(0.1)	2	(0.1)
Chlordiazepoxide	0		1	(0.1)	1	(0.0)
Ethyl Loflazepate	0		1	(0.1)	1	(0.0)
Medazepam	1	(0.1)	0		1	(0.0)
Mexazolam	1	(0.1)	0		1	(0.0)
Other Cardiac Preparations, C01eb	45	(2.4)	33	(1.8)	78	(2.1)
Ubidecarenone	21	(1.1)	18	(1.0)	39	(1.0)
Trimetazidine Hydrochloride	11	(0.6)	11	(0.6)	22	(0.6)
Ranolazine	7	(0.4)	1	(0.1)	8	(0.2)
Ivabradine	1	(0.1)	2	(0.1)	3	(0.1)
Ivabradine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Adenosine Triphosphate, Disodium Salt	2	(0.1)	0		2	(0.1)
Ivabradine Hydrobromide	1	(0.1)	0		1	(0.0)
Ivabradine Oxalate	0		1	(0.1)	1	(0.0)
Trimetazidine	1	(0.1)	0		1	(0.0)
Pregabalin, N03ax16	38	(2.0)	40	(2.1)	78	(2.1)
Pregabalin	38	(2.0)	38	(2.0)	76	(2.0)
Mecobalamin; Pregabalin	0		1	(0.1)	1	(0.0)
Nortriptyline; Pregabalin	0		1	(0.1)	1	(0.0)
Insulins And Analogues For Injection, Intermediate-Acting, A10ac	34	(1.8)	40	(2.1)	74	(2.0)
Insulin Human Injection, Isophane	29	(1.5)	31	(1.6)	60	(1.6)
Isophane Insulin	5	(0.3)	9	(0.5)	14	(0.4)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Blood Glucose Lowering Drugs, Excl. Insulins, A10bx	32	(1.7)	42	(2.2)	74	(2.0)
Repaglinide	19	(1.0)	23	(1.2)	42	(1.1)
Mitiglinide Calcium	8	(0.4)	11	(0.6)	19	(0.5)
Nateglinide	2	(0.1)	6	(0.3)	8	(0.2)
Saroglitazar	1	(0.1)	1	(0.1)	2	(0.1)
Biotin; Chromium; Cinnamomum Spp.	1	(0.1)	0		1	(0.0)
Bromocriptine	0		1	(0.1)	1	(0.0)
Bromocriptine Mesilate	0		1	(0.1)	1	(0.0)
Mitiglinide	1	(0.1)	0		1	(0.0)
Piperazine Derivatives, R06ae	35	(1.9)	39	(2.1)	74	(2.0)
Cetirizine Hydrochloride	23	(1.2)	19	(1.0)	42	(1.1)
Cetirizine	6	(0.3)	10	(0.5)	16	(0.4)
Levocetirizine Dihydrochloride	5	(0.3)	7	(0.4)	12	(0.3)
Levocetirizine	2	(0.1)	3	(0.2)	5	(0.1)
Various Alimentary Tract And Metabolism Products, A16ax	45	(2.4)	28	(1.5)	73	(1.9)
Thioctic Acid	41	(2.2)	24	(1.3)	65	(1.7)
Folic Acid; Mecobalamin; Pyridoxine Hydrochloride; Thioctic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Antioxidants Nos	1	(0.1)	0		1	(0.0)
Chromium Picolinate; Cinnamomum Cassia Bark	1	(0.1)	0		1	(0.0)
Folic Acid; Mecobalamin; Pregabalin; Pyridoxine Hydrochloride; Thioctic Acid	0		1	(0.1)	1	(0.0)
Mecobalamin; Thioctic Acid	1	(0.1)	0		1	(0.0)
Thioctic Acid Tromethamine	0		1	(0.1)	1	(0.0)
Imidazoline Receptor Agonists, C02ac	31	(1.6)	37	(2.0)	68	(1.8)
Moxonidine	19	(1.0)	11	(0.6)	30	(0.8)
Clonidine	5	(0.3)	8	(0.4)	13	(0.3)
Rilmenidine	4	(0.2)	9	(0.5)	13	(0.3)
Clonidine Hydrochloride	2	(0.1)	5	(0.3)	7	(0.2)
Rilmenidine Phosphate	1	(0.1)	4	(0.2)	5	(0.1)
Organic Nitrates, C01da	39	(2.1)	26	(1.4)	65	(1.7)
Glyceryl Trinitrate	22	(1.2)	21	(1.1)	43	(1.1)
Isosorbide Mononitrate	19	(1.0)	6	(0.3)	25	(0.7)
Isosorbide	2	(0.1)	2	(0.1)	4	(0.1)
Isosorbide Dinitrate	1	(0.1)	1	(0.1)	2	(0.1)
Acetic Acid Derivatives And Related Substances, M01ab	27	(1.4)	36	(1.9)	63	(1.7)
Diclofenac	15	(0.8)	12	(0.6)	27	(0.7)
Diclofenac Sodium	5	(0.3)	7	(0.4)	12	(0.3)
Indometacin	2	(0.1)	8	(0.4)	10	(0.3)
Etodolac	0		4	(0.2)	4	(0.1)
Aceclofenac	2	(0.1)	1	(0.1)	3	(0.1)
Bromfenac Sodium	0		3	(0.2)	3	(0.1)
Diclofenac Potassium	2	(0.1)	0		2	(0.1)
Sulindac	1	(0.1)	1	(0.1)	2	(0.1)
Cyanocobalamin; Diclofenac Sodium; Pyridoxine Hydrochloride; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Diclofenac Diethylamine	1	(0.1)	0		1	(0.0)
Diclofenac Sodium; Misoprostol	0		1	(0.1)	1	(0.0)
Corticosteroids, R01ad	32	(1.7)	29	(1.5)	61	(1.6)
Fluticasone Propionate	32	(1.7)	29	(1.5)	61	(1.6)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics, C09da	26	(1.4)	30	(1.6)	56	(1.5)
Hydrochlorothiazide; Losartan Potassium	8	(0.4)	9	(0.5)	17	(0.5)
Hydrochlorothiazide; Telmisartan	5	(0.3)	7	(0.4)	12	(0.3)
Hydrochlorothiazide; Valsartan	4	(0.2)	8	(0.4)	12	(0.3)
Candesartan Cilexetil; Hydrochlorothiazide	3	(0.2)	1	(0.1)	4	(0.1)
Hydrochlorothiazide; Irbesartan	2	(0.1)	1	(0.1)	3	(0.1)
Azilsartan Kamedoxomil; Chlortalidone	1	(0.1)	1	(0.1)	2	(0.1)
Hydrochlorothiazide; Losartan	0		2	(0.1)	2	(0.1)
Hydrochlorothiazide; Olmesartan Medoxomil	1	(0.1)	1	(0.1)	2	(0.1)
Azilsartan Medoxomil; Chlortalidone	1	(0.1)	0		1	(0.0)
Candesartan; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Insulins And Analogues For Injection, Fast-Acting, A10ab	25	(1.3)	31	(1.6)	56	(1.5)
Insulin Glulisine	25	(1.3)	31	(1.6)	56	(1.5)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers, C09db	31	(1.6)	24	(1.3)	55	(1.5)
Amlodipine Besilate; Irbesartan	8	(0.4)	3	(0.2)	11	(0.3)
Amlodipine Besilate; Telmisartan	5	(0.3)	4	(0.2)	9	(0.2)
Amlodipine Besilate; Valsartan	5	(0.3)	4	(0.2)	9	(0.2)
Amlodipine Besilate; Azilsartan	4	(0.2)	4	(0.2)	8	(0.2)
Amlodipine Besilate; Candesartan Cilexetil	4	(0.2)	1	(0.1)	5	(0.1)
Azelnidipine; Olmesartan Medoxomil	1	(0.1)	3	(0.2)	4	(0.1)
Amlodipine Besilate; Olmesartan Medoxomil	1	(0.1)	2	(0.1)	3	(0.1)
Amlodipine; Telmisartan	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine; Valsartan	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine; Olmesartan	1	(0.1)	0		1	(0.0)
Cilnidipine; Telmisartan	0		1	(0.1)	1	(0.0)
Benzodiazepine Related Drugs, N05cf	27	(1.4)	27	(1.4)	54	(1.4)
Zolpidem Tartrate	14	(0.7)	13	(0.7)	27	(0.7)
Zolpidem	5	(0.3)	10	(0.5)	15	(0.4)
Zopiclone	5	(0.3)	3	(0.2)	8	(0.2)
Eszopiclone	3	(0.2)	2	(0.1)	5	(0.1)
H2-Receptor Antagonists, A02ba	28	(1.5)	26	(1.4)	54	(1.4)
Famotidine	22	(1.2)	23	(1.2)	45	(1.2)
Ranitidine	4	(0.2)	1	(0.1)	5	(0.1)
Lafutidine	2	(0.1)	2	(0.1)	4	(0.1)
Magnesium, A12cc	34	(1.8)	20	(1.1)	54	(1.4)
Magnesium	31	(1.6)	18	(1.0)	49	(1.3)
Magnesium Aspartate	0		1	(0.1)	1	(0.0)
Magnesium Aspartate Hydrochloride	1	(0.1)	0		1	(0.0)
Magnesium Aspartate; Magnesium Citrate; Magnesium Oxide	1	(0.1)	0		1	(0.0)
Magnesium Malate	0		1	(0.1)	1	(0.0)
Magnesium; Magnesium Carbonate; Magnesium Citrate; Magnesium Phosphate	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics, R03ak	23	(1.2)	26	(1.4)	49	(1.3)
Budesonide; Formoterol Fumarate	10	(0.5)	11	(0.6)	21	(0.6)
Fluticasone Propionate; Salmeterol Xinafoate	3	(0.2)	7	(0.4)	10	(0.3)
Fluticasone Furoate; Vilanterol Trifenatate	4	(0.2)	5	(0.3)	9	(0.2)
Beclometasone Dipropionate; Formoterol Fumarate	2	(0.1)	1	(0.1)	3	(0.1)
Formoterol Fumarate; Mometasone Furoate	1	(0.1)	1	(0.1)	2	(0.1)
Budesonide; Formoterol Fumarate Dihydrate	0		1	(0.1)	1	(0.0)
Fluticasone Furoate; Vilanterol	1	(0.1)	0		1	(0.0)
Fluticasone Propionate; Formoterol Fumarate	1	(0.1)	0		1	(0.0)
Fluticasone Propionate; Salmeterol	1	(0.1)	0		1	(0.0)
Alpha-Adrenoreceptor Antagonists, C02ca	30	(1.6)	19	(1.0)	49	(1.3)
Doxazosin Mesilate	13	(0.7)	11	(0.6)	24	(0.6)
Doxazosin	12	(0.6)	8	(0.4)	20	(0.5)
Urapidil	6	(0.3)	1	(0.1)	7	(0.2)
Beta Blocking Agents, Non-Selective, C07aa	26	(1.4)	23	(1.2)	49	(1.3)
Propranolol	10	(0.5)	9	(0.5)	19	(0.5)
Timolol	6	(0.3)	8	(0.4)	14	(0.4)
Propranolol Hydrochloride	5	(0.3)	0		5	(0.1)
Sotalol	3	(0.2)	2	(0.1)	5	(0.1)
Sotalol Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Nadolol	0		2	(0.1)	2	(0.1)
Timolol Maleate	1	(0.1)	0		1	(0.0)
Other Centrally Acting Agents, M03bx	27	(1.4)	21	(1.1)	48	(1.3)
Cyclobenzaprine Hydrochloride	8	(0.4)	5	(0.3)	13	(0.3)
Tizanidine Hydrochloride	5	(0.3)	4	(0.2)	9	(0.2)
Tizanidine	5	(0.3)	3	(0.2)	8	(0.2)
Cyclobenzaprine	3	(0.2)	4	(0.2)	7	(0.2)
Baclofen	3	(0.2)	3	(0.2)	6	(0.2)
Thiocolchicoside	2	(0.1)	1	(0.1)	3	(0.1)
Afloqualone	0		1	(0.1)	1	(0.0)
Eperisone Hydrochloride	1	(0.1)	0		1	(0.0)
Fenyramidol Hydrochloride	1	(0.1)	0		1	(0.0)
Drugs For Urinary Frequency And Incontinence, G04bd	29	(1.5)	18	(1.0)	47	(1.2)
Mirabegron	9	(0.5)	5	(0.3)	14	(0.4)
Oxybutynin	4	(0.2)	4	(0.2)	8	(0.2)
Solifenacin Succinate	3	(0.2)	4	(0.2)	7	(0.2)
Fesoterodine Fumarate	3	(0.2)	1	(0.1)	4	(0.1)
Solifenacin	3	(0.2)	1	(0.1)	4	(0.1)
Vibegron	2	(0.1)	2	(0.1)	4	(0.1)
Oxybutynin Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Tolterodine L-Tartrate	2	(0.1)	0		2	(0.1)
Darifenacin	0		1	(0.1)	1	(0.0)
Flavoxate Hydrochloride	1	(0.1)	0		1	(0.0)
Propiverine Hydrochloride	1	(0.1)	0		1	(0.0)
Non-Selective Monoamine Reuptake Inhibitors, N06aa	23	(1.2)	24	(1.3)	47	(1.2)
Amitriptyline	15	(0.8)	10	(0.5)	25	(0.7)
Amitriptyline Hydrochloride	3	(0.2)	4	(0.2)	7	(0.2)
Nortriptyline	3	(0.2)	3	(0.2)	6	(0.2)
Nortriptyline Hydrochloride	0		4	(0.2)	4	(0.1)
Opipramol Hydrochloride	0		2	(0.1)	2	(0.1)
Amoxapine	1	(0.1)	0		1	(0.0)
Imipramine	1	(0.1)	0		1	(0.0)
Opipramol	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Leukotriene Receptor Antagonists, R03dc	22	(1.2)	24	(1.3)	46	(1.2)
Montelukast Sodium	12	(0.6)	16	(0.8)	28	(0.8)
Montelukast	10	(0.5)	7	(0.4)	17	(0.5)
Pranlukast Hydrate	0		1	(0.1)	1	(0.0)
Vitamin K Antagonists, B01aa	25	(1.3)	18	(1.0)	43	(1.1)
Warfarin	12	(0.6)	9	(0.5)	21	(0.6)
Acenocoumarol	9	(0.5)	1	(0.1)	10	(0.3)
Warfarin Sodium	3	(0.2)	5	(0.3)	8	(0.2)
Phenprocoumon	0		3	(0.2)	3	(0.1)
Warfarin Potassium	1	(0.1)	0		1	(0.0)
Folic Acid And Derivatives, B03bb	22	(1.2)	20	(1.1)	42	(1.1)
Folic Acid	22	(1.2)	18	(1.0)	40	(1.1)
Calcium; Calcium Ascorbate; Calcium L-Threonate; Colecalciferol; Docosahexaenoic Acid; Eicosapentaenoic Acid; Ferrous Asparto Glycinate; Folic Acid; Iron; Linolenic Acid; Pyridoxine Hydrochloride; Tocopheryl Ace	0		1	(0.1)	1	(0.0)
Folic Acid; Vitamins Nos	0		1	(0.1)	1	(0.0)
Magnesium Compounds, A02aa	17	(0.9)	24	(1.3)	41	(1.1)
Magnesium Oxide	14	(0.7)	14	(0.8)	28	(0.8)
Magnesium Hydroxide	3	(0.2)	9	(0.5)	12	(0.3)
Magnesium Carbonate; Magnesium Oxide	0		1	(0.1)	1	(0.0)
Beta Blocking Agents, S01ed	23	(1.2)	17	(0.9)	40	(1.1)
Dorzolamide Hydrochloride; Timolol Maleate	7	(0.4)	10	(0.5)	17	(0.5)
Brimonidine Tartrate; Timolol Maleate	3	(0.2)	3	(0.2)	6	(0.2)
Latanoprost; Timolol Maleate	5	(0.3)	1	(0.1)	6	(0.2)
Bimatoprost; Timolol Maleate	2	(0.1)	0		2	(0.1)
Brinzolamide; Timolol Maleate	0		2	(0.1)	2	(0.1)
Tafluprost; Timolol Maleate	1	(0.1)	1	(0.1)	2	(0.1)
Timolol Maleate; Travoprost	2	(0.1)	0		2	(0.1)
Brimonidine; Timolol	1	(0.1)	0		1	(0.0)
Dorzolamide Hydrochloride; Timolol	1	(0.1)	0		1	(0.0)
Timolol; Travoprost	1	(0.1)	0		1	(0.0)
Testosterone-5-Alpha Reductase Inhibitors, G04cb	23	(1.2)	17	(0.9)	40	(1.1)
Finasteride	17	(0.9)	9	(0.5)	26	(0.7)
Dutasteride	6	(0.3)	8	(0.4)	14	(0.4)
3-Oxoandrosten (4) Derivatives, G03ba	24	(1.3)	15	(0.8)	39	(1.0)
Testosterone	17	(0.9)	9	(0.5)	26	(0.7)
Testosterone Cipionate	6	(0.3)	4	(0.2)	10	(0.3)
Testosterone Undecanoate	1	(0.1)	2	(0.1)	3	(0.1)
Tadalafil, G04be08	19	(1.0)	20	(1.1)	39	(1.0)
Tadalafil	19	(1.0)	20	(1.1)	39	(1.0)
Ace Inhibitors And Diuretics, C09ba	17	(0.9)	21	(1.1)	38	(1.0)
Indapamide; Perindopril Erbumine	4	(0.2)	6	(0.3)	10	(0.3)
Hydrochlorothiazide; Lisinopril	3	(0.2)	5	(0.3)	8	(0.2)
Indapamide; Perindopril Arginine	3	(0.2)	4	(0.2)	7	(0.2)
Enalapril Maleate; Hydrochlorothiazide	1	(0.1)	2	(0.1)	3	(0.1)
Indapamide; Perindopril	2	(0.1)	1	(0.1)	3	(0.1)
Indapamide; Perindopril Tosilate	1	(0.1)	2	(0.1)	3	(0.1)
Hydrochlorothiazide; Ramipril	1	(0.1)	1	(0.1)	2	(0.1)
Hydrochlorothiazide; Lisinopril Dihydrate	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Zofenopril Calcium	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Natural And Semisynthetic Estrogens, Plain, G03ca	15	(0.8)	20	(1.1)	35	(0.9)
Estradiol	8	(0.4)	9	(0.5)	17	(0.5)
Estrogens Conjugated	4	(0.2)	4	(0.2)	8	(0.2)
Ethinylestradiol	2	(0.1)	4	(0.2)	6	(0.2)
Estriol	0		2	(0.1)	2	(0.1)
Dienogest; Estradiol Valerate	0		1	(0.1)	1	(0.0)
Dydrogesterone; Estradiol Hemihydrate	1	(0.1)	0		1	(0.0)
Estradiol; Estriol	0		1	(0.1)	1	(0.0)
Estradiol; Norethisterone	1	(0.1)	0		1	(0.0)
Potassium, A12ba	16	(0.8)	18	(1.0)	34	(0.9)
Potassium Chloride	15	(0.8)	18	(1.0)	33	(0.9)
Boric Acid; Potassium Chloride; Sodium Carbonate Anhydrous; Sodium Chloride; Sodium Phosphate Dibasic	1	(0.1)	0		1	(0.0)
Oxicams, M01ac	18	(1.0)	15	(0.8)	33	(0.9)
Meloxicam	17	(0.9)	15	(0.8)	32	(0.8)
Ampiroxicam	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Plain, A11ea	15	(0.8)	18	(1.0)	33	(0.9)
Vitamin B Complex	12	(0.6)	18	(1.0)	30	(0.8)
Vitamin B-Complex, Plain	2	(0.1)	0		2	(0.1)
Calcium Pantothenate; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Mononitrate	1	(0.1)	0		1	(0.0)
Combinations Of Various Lipid Modifying Agents, C10ba	9	(0.5)	23	(1.2)	32	(0.8)
Ezetimibe; Rosuvastatin Calcium	4	(0.2)	7	(0.4)	11	(0.3)
Atorvastatin Calcium; Ezetimibe	3	(0.2)	4	(0.2)	7	(0.2)
Fenofibrate; Pravastatin Sodium	2	(0.1)	3	(0.2)	5	(0.1)
Ezetimibe; Simvastatin	0		4	(0.2)	4	(0.1)
Atorvastatin Calcium; Fenofibrate	0		2	(0.1)	2	(0.1)
Fenofibrate; Rosuvastatin Calcium	0		2	(0.1)	2	(0.1)
Atorvastatin; Fenofibrate	0		1	(0.1)	1	(0.0)
Iron Bivalent, Oral Preparations, B03aa	14	(0.7)	18	(1.0)	32	(0.8)
Ferrous Sulfate	8	(0.4)	10	(0.5)	18	(0.5)
Ferrous Fumarate	5	(0.3)	2	(0.1)	7	(0.2)
Ferrous Sodium Citrate	0		4	(0.2)	4	(0.1)
Ferrous Gluconate	1	(0.1)	2	(0.1)	3	(0.1)
Other Ophthalmologicals, S01xa	15	(0.8)	16	(0.8)	31	(0.8)
Pirenoxine	4	(0.2)	6	(0.3)	10	(0.3)
Diquafosol Tetrasodium	3	(0.2)	2	(0.1)	5	(0.1)
Xantofyl	3	(0.2)	1	(0.1)	4	(0.1)
Xantofyl; Zeaxanthin	1	(0.1)	3	(0.2)	4	(0.1)
Ascorbic Acid; Cupric Oxide; Dl-Alpha Tocopheryl Acetate; Xantofyl; Zeaxanthin; Zinc Oxide	2	(0.1)	1	(0.1)	3	(0.1)
Macrogol 400; Propylene Glycol	0		2	(0.1)	2	(0.1)
Diquafosol	1	(0.1)	0		1	(0.0)
Pirenoxine Sodium	0		1	(0.1)	1	(0.0)
Polyvinyl Alcohol	1	(0.1)	0		1	(0.0)
Zeaxanthin	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Calcium, Combinations With Vitamin D And/Or Other Drugs, A12ax	11	(0.6)	19	(1.0)	30	(0.8)
Calcium Carbonate; Colecalciferol	5	(0.3)	9	(0.5)	14	(0.4)
Calcium; Colecalciferol	3	(0.2)	3	(0.2)	6	(0.2)
Calcium Carbonate; Colecalciferol; Menaquinone	0		2	(0.1)	2	(0.1)
Calcium; Magnesium; Zinc	1	(0.1)	1	(0.1)	2	(0.1)
Calcitriol; Calcium Carbonate; Zinc	0		1	(0.1)	1	(0.0)
Calcium Carbonate; Colecalciferol; Magnesium	1	(0.1)	0		1	(0.0)
Calcium Citrate; Colecalciferol	0		1	(0.1)	1	(0.0)
Calcium Phosphate; Colecalciferol	0		1	(0.1)	1	(0.0)
Calcium, Combinations With Vitamin D And/Or Other Drugs	0		1	(0.1)	1	(0.0)
Calcium; Colecalciferol; Magnesium	1	(0.1)	0		1	(0.0)
Opioids In Combination With Non-Opioid Analgesics, N02aj	16	(0.8)	14	(0.8)	30	(0.8)
Hydrocodone Bitartrate; Paracetamol	5	(0.3)	5	(0.3)	10	(0.3)
Codeine Phosphate; Paracetamol	5	(0.3)	2	(0.1)	7	(0.2)
Oxycodone Hydrochloride; Paracetamol	1	(0.1)	4	(0.2)	5	(0.1)
Paracetamol; Tramadol Hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Caffeine; Codeine; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Hydrocodone; Paracetamol	2	(0.1)	0		2	(0.1)
Dexketoprofen Trometamol; Tramadol Hydrochloride	0		1	(0.1)	1	(0.0)
Other Opioids, N02ax	17	(0.9)	13	(0.7)	30	(0.8)
Tramadol	14	(0.7)	10	(0.5)	24	(0.6)
Tramadol Hydrochloride	3	(0.2)	3	(0.2)	6	(0.2)
Benzothiazepine Derivatives, C08db	17	(0.9)	12	(0.6)	29	(0.8)
Diltiazem	13	(0.7)	7	(0.4)	20	(0.5)
Diltiazem Hydrochloride	4	(0.2)	5	(0.3)	9	(0.2)
Other Plain Vitamin Preparations, A11ha	12	(0.6)	14	(0.8)	26	(0.7)
Biotin	12	(0.6)	13	(0.7)	25	(0.7)
Adenine Hydrochloride	0		1	(0.1)	1	(0.0)
Benzodiazepine Derivatives, N03ae	12	(0.6)	13	(0.7)	25	(0.7)
Clonazepam	12	(0.6)	13	(0.7)	25	(0.7)
Bile Acids And Derivatives, A05aa	15	(0.8)	10	(0.5)	25	(0.7)
Ursodeoxycholic Acid	15	(0.8)	10	(0.5)	25	(0.7)
Progestogens, G03ac	10	(0.5)	15	(0.8)	25	(0.7)
Desogestrel	5	(0.3)	3	(0.2)	8	(0.2)
Levonorgestrel	1	(0.1)	5	(0.3)	6	(0.2)
Medroxyprogesterone Acetate	0		3	(0.2)	3	(0.1)
Norethisterone	2	(0.1)	1	(0.1)	3	(0.1)
Drospirenone	1	(0.1)	0		1	(0.0)
Estrogens Conjugated; Medroxyprogesterone Acetate	1	(0.1)	0		1	(0.0)
Ethinylestradiol; Levonorgestrel	0		1	(0.1)	1	(0.0)
Ethinylestradiol; Norethisterone	0		1	(0.1)	1	(0.0)
Ethinylestradiol; Norethisterone Acetate	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12, A11db	14	(0.7)	11	(0.6)	25	(0.7)
Benfotiamine; Cyanocobalamin; Pyridoxine Hydrochloride	6	(0.3)	3	(0.2)	9	(0.2)
Cyanocobalamin; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	3	(0.2)	3	(0.2)	6	(0.2)
Benfotiamine; Cyanocobalamin; Pyridoxine	2	(0.1)	3	(0.2)	5	(0.1)
Pyridoxine Hydrochloride; Thiamine Mononitrate	0		2	(0.1)	2	(0.1)
Benfotiamine; Cyanocobalamin	1	(0.1)	0		1	(0.0)
Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Vitamin B1 Nos; Vitamin B12 Nos	1	(0.1)	0		1	(0.0)
Anticholinergics, R03bb	18	(1.0)	6	(0.3)	24	(0.6)
Ipratropium Bromide	8	(0.4)	0		8	(0.2)
Tiotropium Bromide Monohydrate	4	(0.2)	3	(0.2)	7	(0.2)
Ipratropium	2	(0.1)	2	(0.1)	4	(0.1)
Tiotropium Bromide	2	(0.1)	0		2	(0.1)
Umeclidinium	2	(0.1)	0		2	(0.1)
Umeclidinium Bromide	1	(0.1)	1	(0.1)	2	(0.1)
Aclidinium Bromide	0		1	(0.1)	1	(0.0)
Diazepines, Oxazepines, Thiazepines And Oxepines, N05ah	14	(0.7)	10	(0.5)	24	(0.6)
Quetiapine Fumarate	10	(0.5)	2	(0.1)	12	(0.3)
Olanzapine	2	(0.1)	4	(0.2)	6	(0.2)
Quetiapine	2	(0.1)	4	(0.2)	6	(0.2)
Multivitamins With Minerals, A11aa	12	(0.6)	12	(0.6)	24	(0.6)
Ascorbic Acid; Calcium; Minerals Nos; Retinol; Tocopheryl Acetate; Vitamin B Nos; Vitamins Nos; Zinc	8	(0.4)	6	(0.3)	14	(0.4)
Multivitamins With Minerals [Umbrella Term]	0		4	(0.2)	4	(0.1)
Ascorbic Acid; Betacarotene; Biotin; Calcium; Chlorine; Chromium; Copper; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Folic Acid; Iodine; Magnesium; Manganese; Molybdenum; Nickel; Nicotinamide; Pantothenic Acid; Phos	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Betacarotene; Biotin; Calcium Carbonate; Calcium Pantothenate; Calcium Phosphate; Calcium Phosphate Dibasic; Chromic Chloride; Cupric Oxide; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ergocalcif	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Betacarotene; Biotin; Calcium Carbonate; Calcium Pantothenate; Chromic Chloride; Colecalciferol; Cupric Oxide; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Folic Acid; Magnesium O	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Biotin; Calcium; Calcium Pantothenate; Chloride; Chromium; Colecalciferol; Copper; Folic Acid; Iodine; Iron; Magnesium; Manganese; Molybdenum; Nickel; Nicotinamide; Phosphorus; Potassium; Pyridoxine Hydr	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate; Colecalciferol; Copper Sulfate; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Folic Acid; Manganese Sulfate; Nicotinamide; Potassium Iodid	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Calcium Phosphate Dibasic; Cupric Oxide; Tocopheryl Acetate; Xantofyl; Zinc Oxide	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Melatonin Receptor Agonists, N05ch	13	(0.7)	10	(0.5)	23	(0.6)
Melatonin	12	(0.6)	10	(0.5)	22	(0.6)
Magnesium; Melatonin	1	(0.1)	0		1	(0.0)
Natural Opium Alkaloids, N02aa	8	(0.4)	15	(0.8)	23	(0.6)
Oxycodone	2	(0.1)	7	(0.4)	9	(0.2)
Hydrocodone	4	(0.2)	4	(0.2)	8	(0.2)
Oxycodone Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Hydromorphone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Morphine Sulfate	0		2	(0.1)	2	(0.1)
Other Viral Vaccines, J07bx	12	(0.6)	11	(0.6)	23	(0.6)
Tozinameran	9	(0.5)	5	(0.3)	14	(0.4)
Elasomeran	2	(0.1)	3	(0.2)	5	(0.1)
Covid-19 Vaccine Nrvv Ad (Chadox1 Ncov-19)	1	(0.1)	2	(0.1)	3	(0.1)
Covid-19 Vaccine	0		1	(0.1)	1	(0.0)
Unspecified Herbal And Traditional Medicine, V90	11	(0.6)	12	(0.6)	23	(0.6)
Malus Spp. Vinegar Extract	5	(0.3)	1	(0.1)	6	(0.2)
Traditional Medicine	1	(0.1)	3	(0.2)	4	(0.1)
Unspecified Herbal	2	(0.1)	1	(0.1)	3	(0.1)
Herbal Preparation	2	(0.1)	0		2	(0.1)
Alisma Orientale Tube; Anemarrhena Asphodeloides Rhizome; Cornus Officinalis Fruit; Dioscorea Polystachya Rhizome; Paeonia X Suffruticosa Root Bark; Phellodendron Amurense Bark; Poria Cocos Sclerotium; Rehma	0		1	(0.1)	1	(0.0)
Allium Sativum Bulb; Borneol; Crataegus Pinnatifida Fruit; Erigeron Breviscapus Herb; Ginkgo Biloba Leaf; Gynostemma Pentaphyllum Whole Plant; Panax Notoginseng Root; Salvia Miltiorrhiza Root	0		1	(0.1)	1	(0.0)
Astragalus Mongholicus Root; Cyathula Officinalis Root; Epimedium Brevicornu Herb; Plantago Asiatica Herb; Typha Angustifolia Pollen	0		1	(0.1)	1	(0.0)
Bacopa Monnieri Herb; Camellia Sinensis Leaf; Curcuma Longa Rhizome; Silybum Marianum Seed; Withania Somnifera Root	0		1	(0.1)	1	(0.0)
Cinnamomum Spp.	0		1	(0.1)	1	(0.0)
Ginseng Nos	0		1	(0.1)	1	(0.0)
Pueraria Montana	0		1	(0.1)	1	(0.0)
Quercus Salicina Extract	0		1	(0.1)	1	(0.0)
Rubus Idaeus Leaf; Sambucus Nigra Flower; Sambucus Nigra Fruit	1	(0.1)	0		1	(0.0)
Traditional Chinese Medicine (Tcm) Decoction	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Antidiarrheal Microorganisms, A07fa	8	(0.4)	14	(0.8)	22	(0.6)
Bifidobacterium Lactis	5	(0.3)	6	(0.3)	11	(0.3)
Bacillus Mesentericus; Clostridium Butyricum; Enterococcus Faecalis	1	(0.1)	2	(0.1)	3	(0.1)
Bacillus Clausii; Bacillus Coagulans; Bacillus Indicus; Bacillus Lichenformis; Bacillus Subtilis	0		1	(0.1)	1	(0.0)
Bacillus Subtilis; Enterococcus Faecalis; Lactobacillus Acidophilus	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum; Bifidobacterium Infantis	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum; Bifidobacterium Lactis; Lactobacillus Acidophilus	1	(0.1)	0		1	(0.0)
Bifidobacterium Longum; Enterococcus Faecalis; Lactobacillus Acidophilus	0		1	(0.1)	1	(0.0)
Bifidobacterium Nos	0		1	(0.1)	1	(0.0)
Saccharomyces Boulardii	1	(0.1)	0		1	(0.0)
Ace Inhibitors And Calcium Channel Blockers, C09bb	11	(0.6)	10	(0.5)	21	(0.6)
Amlodipine Besilate; Perindopril Arginine	4	(0.2)	1	(0.1)	5	(0.1)
Amlodipine Besilate; Ramipril	1	(0.1)	3	(0.2)	4	(0.1)
Amlodipine Besilate; Benazepril Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Amlodipine Besilate; Lisinopril	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Perindopril Erbumine	1	(0.1)	1	(0.1)	2	(0.1)
Enalapril Maleate; Lercanidipine Hydrochloride	2	(0.1)	0		2	(0.1)
Amlodipine Besilate; Perindopril Tosilate	0		1	(0.1)	1	(0.0)
Amlodipine; Benazepril	0		1	(0.1)	1	(0.0)
Trandolapril; Verapamil Hydrochloride	1	(0.1)	0		1	(0.0)
Benzodiazepine Derivatives, N05cd	11	(0.6)	10	(0.5)	21	(0.6)
Temazepam	4	(0.2)	3	(0.2)	7	(0.2)
Brotizolam	3	(0.2)	2	(0.1)	5	(0.1)
Estazolam	1	(0.1)	1	(0.1)	2	(0.1)
Flunitrazepam	0		2	(0.1)	2	(0.1)
Triazolam	1	(0.1)	1	(0.1)	2	(0.1)
Loprazolam Mesilate	1	(0.1)	0		1	(0.0)
Lormetazepam	0		1	(0.1)	1	(0.0)
Midazolam	1	(0.1)	0		1	(0.0)
Nitrazepam	1	(0.1)	0		1	(0.0)
Rilmazafone Hydrochloride	0		1	(0.1)	1	(0.0)
Centrally Acting Sympathomimetics, N06ba	7	(0.4)	14	(0.8)	21	(0.6)
Amfetamine Aspartate; Amfetamine Sulfate; Dexamfetamine Saccharate; Dexamfetamine Sulfate	2	(0.1)	5	(0.3)	7	(0.2)
Modafinil	3	(0.2)	1	(0.1)	4	(0.1)
Dexamfetamine	1	(0.1)	2	(0.1)	3	(0.1)
Armodafinil	1	(0.1)	1	(0.1)	2	(0.1)
Lisdexamfetamine Mesilate	0		2	(0.1)	2	(0.1)
Atomoxetine	1	(0.1)	0		1	(0.0)
Atomoxetine Hydrochloride	1	(0.1)	0		1	(0.0)
Dexamfetamine Sulfate	0		1	(0.1)	1	(0.0)
Methylphenidate	0		1	(0.1)	1	(0.0)
Methylphenidate Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02bx	8	(0.4)	12	(0.6)	20	(0.5)
Rebamipide	4	(0.2)	9	(0.5)	13	(0.3)
Bismuth Subsalicylate	2	(0.1)	0		2	(0.1)
Irsogladine Maleate	1	(0.1)	1	(0.1)	2	(0.1)
Benexate Hcl Beta-Cyclodextrin Clathrate	0		1	(0.1)	1	(0.0)
Bismuth Oxide; Bismuth Subgallate; Zinc Oxide	0		1	(0.1)	1	(0.0)
Calcium Carbonate; Magnesium Carbonate; Sodium Alginate	1	(0.1)	0		1	(0.0)
Bisphosphonates, M05ba	11	(0.6)	7	(0.4)	18	(0.5)
Alendronate Sodium	4	(0.2)	3	(0.2)	7	(0.2)
Minodronic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Alendronic Acid	2	(0.1)	0		2	(0.1)
Ibandronate Sodium	2	(0.1)	0		2	(0.1)
Risedronate Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Clodronate Disodium	0		1	(0.1)	1	(0.0)
Risedronic Acid	1	(0.1)	0		1	(0.0)
Digitalis Glycosides, C01aa	10	(0.5)	8	(0.4)	18	(0.5)
Digoxin	10	(0.5)	5	(0.3)	15	(0.4)
Metildigoxin	0		2	(0.1)	2	(0.1)
Digitoxin	0		1	(0.1)	1	(0.0)
Antiarrhythmics, Class Iii, C01bd	11	(0.6)	6	(0.3)	17	(0.5)
Amiodarone Hydrochloride	5	(0.3)	3	(0.2)	8	(0.2)
Amiodarone	5	(0.3)	1	(0.1)	6	(0.2)
Dofetilide	1	(0.1)	1	(0.1)	2	(0.1)
Dronedarone	0		1	(0.1)	1	(0.0)
Bioflavonoids, C05ca	9	(0.5)	8	(0.4)	17	(0.5)
Diosmin	5	(0.3)	5	(0.3)	10	(0.3)
Diosmin; Hesperidin	4	(0.2)	2	(0.1)	6	(0.2)
Ascorbic Acid; Rutoside	0		1	(0.1)	1	(0.0)
Carbonic Anhydrase Inhibitors, S01ec	8	(0.4)	9	(0.5)	17	(0.5)
Brinzolamide	4	(0.2)	3	(0.2)	7	(0.2)
Dorzolamide	2	(0.1)	5	(0.3)	7	(0.2)
Dorzolamide Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Brimonidine Tartrate; Brinzolamide	1	(0.1)	0		1	(0.0)
Contact Laxatives, A06ab	4	(0.2)	13	(0.7)	17	(0.5)
Sennoside A+B	2	(0.1)	5	(0.3)	7	(0.2)
Sennoside A+B Calcium	1	(0.1)	5	(0.3)	6	(0.2)
Sodium Picosulfate	0		3	(0.2)	3	(0.1)
Docusate Sodium; Senna Alexandrina	1	(0.1)	0		1	(0.0)
Dopamine Agonists, N04bc	9	(0.5)	8	(0.4)	17	(0.5)
Pramipexole	3	(0.2)	3	(0.2)	6	(0.2)
Ropinirole	2	(0.1)	3	(0.2)	5	(0.1)
Pramipexole Dihydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Pramipexole Dihydrochloride Monohydrate	1	(0.1)	0		1	(0.0)
Ropinirole Hydrochloride	1	(0.1)	0		1	(0.0)
Other Antipsychotics, N05ax	7	(0.4)	10	(0.5)	17	(0.5)
Aripiprazole	5	(0.3)	6	(0.3)	11	(0.3)
Risperidone	2	(0.1)	4	(0.2)	6	(0.2)
Aminoalkyl Ethers, R06aa	10	(0.5)	6	(0.3)	16	(0.4)
Diphenhydramine Hydrochloride	7	(0.4)	3	(0.2)	10	(0.3)
Diphenhydramine	3	(0.2)	0		3	(0.1)
Diphenhydramine Hydrochloride; Paracetamol	0		3	(0.2)	3	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Purine Derivatives, C04ad	11	(0.6)	5	(0.3)	16	(0.4)
Pentoxifylline	11	(0.6)	5	(0.3)	16	(0.4)
Azaspirodecanedione Derivatives, N05be	6	(0.3)	9	(0.5)	15	(0.4)
Buspirone Hydrochloride	5	(0.3)	3	(0.2)	8	(0.2)
Buspirone	1	(0.1)	6	(0.3)	7	(0.2)
Multivitamins, Other Combinations, A11ab	8	(0.4)	7	(0.4)	15	(0.4)
Ascorbic Acid; Ergocalciferol; Folic Acid; Nicotinamide; Panthenol; Retinol; Riboflavin; Thiamine Hydrochloride	4	(0.2)	5	(0.3)	9	(0.2)
Ascorbic Acid; Betacarotene; Bioflavonoids Nos; Biotin; Calcium Citrate; Calcium Pantothenate; Choline Bitartrate; Chromium Picolinate; Colecalciferol; Copper Gluconate; Cyanocobalamin; Dl-Alpha Tocopheryl Aceta	1	(0.1)	1	(0.1)	2	(0.1)
Multivitamins, Other Combinations	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Betacarotene; Biotin; Boron; Calcium; Calcium Pantothenate; Chloride; Chromium; Colecalciferol; Copper; Cyanocobalamin; Folic Acid; Iodine; Iron; Lycopene; Magnesium; Manganese; Molybdenum; Nickel; Nicoti	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium; Colecalciferol; Copper; Ferrous Fumarate; Folic Acid; Iodine; Magnesium; Manganese; Nicotinamide; Panax Ginseng Root; Pantothenic Acid; Phosphorus; Potassium; Pyridoxine Hydrochloride; Retino	1	(0.1)	0		1	(0.0)
Antivertigo Preparations, N07ca	7	(0.4)	7	(0.4)	14	(0.4)
Betahistine Hydrochloride	2	(0.1)	4	(0.2)	6	(0.2)
Betahistine	2	(0.1)	3	(0.2)	5	(0.1)
Acetylleucine	1	(0.1)	0		1	(0.0)
Betahistine Mesilate	1	(0.1)	0		1	(0.0)
Cinnarizine	1	(0.1)	0		1	(0.0)
Nicotinic Acid And Derivatives, C10ad	8	(0.4)	6	(0.3)	14	(0.4)
Nicotinic Acid	5	(0.3)	4	(0.2)	9	(0.2)
Tocopheryl Nicotinate	3	(0.2)	1	(0.1)	4	(0.1)
Acipimox	0		1	(0.1)	1	(0.0)
Other Antiepileptics, N03ax	7	(0.4)	7	(0.4)	14	(0.4)
Topiramate	3	(0.2)	7	(0.4)	10	(0.3)
Levetiracetam	4	(0.2)	0		4	(0.1)
Other Immunosuppressants, L04ax	9	(0.5)	5	(0.3)	14	(0.4)
Methotrexate	7	(0.4)	4	(0.2)	11	(0.3)
Azathioprine	1	(0.1)	1	(0.1)	2	(0.1)
Methotrexate Sodium	1	(0.1)	0		1	(0.0)
Other Psychostimulants And Nootropics, N06bx	7	(0.4)	7	(0.4)	14	(0.4)
Piracetam	4	(0.2)	3	(0.2)	7	(0.2)
Vinpocetine	3	(0.2)	4	(0.2)	7	(0.2)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamins, Other Combinations, A11jc	5	(0.3)	9	(0.5)	14	(0.4)
Colecalciferol; Folic Acid; Mecobalamin; Pyridoxine Hydrochloride; Thioctic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Vitamins, Other Combinations	0		3	(0.2)	3	(0.1)
Ascorbic Acid; Betacarotene; Calcium Carbonate; Calcium Pantothenate; Calcium Silicate; Cellulose Microcrystalline; Colecalciferol; Croscarmellose Sodium; Cyanocobalamin; Dextrin; Dl-Alpha Tocopheryl Acetate; Fe	0		2	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate Dibasic; Colecalciferol; Copper Sulfate; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Magnesium Oxide; Manganese Sulfate; Nicotinamide; Po	1	(0.1)	1	(0.1)	2	(0.1)
Biotin; Calcium Carbonate; Gelatine Hydrolysate	1	(0.1)	0		1	(0.0)
Minerals Nos; Omega-3 Fatty Acids; Vitamins Nos	1	(0.1)	0		1	(0.0)
Pyridoxine Hydrochloride; Thioctic Acid; Vitamin B1 Nos; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Selenium; Thioctic Acid; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Antiarrhythmics, Class Ic, C01bc	6	(0.3)	7	(0.4)	13	(0.3)
Propafenone Hydrochloride	2	(0.1)	4	(0.2)	6	(0.2)
Flecainide Acetate	2	(0.1)	1	(0.1)	3	(0.1)
Flecainide	1	(0.1)	1	(0.1)	2	(0.1)
Propafenone	1	(0.1)	1	(0.1)	2	(0.1)
Coxibs, M01ah	4	(0.2)	9	(0.5)	13	(0.3)
Celecoxib	4	(0.2)	8	(0.4)	12	(0.3)
Etoricoxib	0		1	(0.1)	1	(0.0)
Other Potassium-Sparing Agents, C03db	8	(0.4)	5	(0.3)	13	(0.3)
Triamterene	5	(0.3)	3	(0.2)	8	(0.2)
Amiloride	3	(0.2)	1	(0.1)	4	(0.1)
Amiloride Hydrochloride	0		1	(0.1)	1	(0.0)
Phenylalkylamine Derivatives, C08da	3	(0.2)	10	(0.5)	13	(0.3)
Verapamil	2	(0.1)	5	(0.3)	7	(0.2)
Verapamil Hydrochloride	1	(0.1)	5	(0.3)	6	(0.2)
Selective Serotonin (5ht1) Agonists, N02cc	6	(0.3)	7	(0.4)	13	(0.3)
Sumatriptan	5	(0.3)	4	(0.2)	9	(0.2)
Rizatriptan Benzoate	0		2	(0.1)	2	(0.1)
Eletriptan Hydrobromide	1	(0.1)	0		1	(0.0)
Rizatriptan	0		1	(0.1)	1	(0.0)
Other Vasodilators Used In Cardiac Diseases, C01dx	5	(0.3)	7	(0.4)	12	(0.3)
Nicorandil	3	(0.2)	4	(0.2)	7	(0.2)
Sacubitril	1	(0.1)	2	(0.1)	3	(0.1)
Molsidomine	1	(0.1)	1	(0.1)	2	(0.1)
Ace Inhibitors, Other Combinations, C09bx	7	(0.4)	4	(0.2)	11	(0.3)
Amlodipine Besilate; Indapamide; Perindopril Arginine	7	(0.4)	1	(0.1)	8	(0.2)
Amlodipine Besilate; Indapamide; Perindopril Erbumine	0		2	(0.1)	2	(0.1)
Metoprolol Tartrate; Ramipril	0		1	(0.1)	1	(0.0)
Diphenylmethane Derivatives, N05bb	8	(0.4)	3	(0.2)	11	(0.3)
Hydroxyzine	7	(0.4)	2	(0.1)	9	(0.2)
Hydroxyzine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Direct Thrombin Inhibitors, B01ae	6	(0.3)	5	(0.3)	11	(0.3)
Dabigatran Etexilate Mesilate	5	(0.3)	3	(0.2)	8	(0.2)
Dabigatran	1	(0.1)	1	(0.1)	2	(0.1)
Dabigatran Etexilate	0		1	(0.1)	1	(0.0)
Lipid Modifying Agents In Combination With Other Drugs, C10bx	5	(0.3)	6	(0.3)	11	(0.3)
Olmesartan Medoxomil; Rosuvastatin Calcium	1	(0.1)	2	(0.1)	3	(0.1)
Acetylsalicylic Acid; Atorvastatin Calcium	1	(0.1)	1	(0.1)	2	(0.1)
Acetylsalicylic Acid; Atorvastatin	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Rosuvastatin Calcium	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Atorvastatin Calcium; Perindopril Arginine	0		1	(0.1)	1	(0.0)
Amlodipine Besilate; Rosuvastatin Calcium; Telmisartan	0		1	(0.1)	1	(0.0)
Candesartan Cilexetil; Rosuvastatin Calcium	1	(0.1)	0		1	(0.0)
Fish Oil; Ubidecarenone	0		1	(0.1)	1	(0.0)
Propulsives, A03fa	2	(0.1)	9	(0.5)	11	(0.3)
Domperidone	2	(0.1)	7	(0.4)	9	(0.2)
Cinitapride	0		1	(0.1)	1	(0.0)
Mosapride Citrate	0		1	(0.1)	1	(0.0)
Serotonin (5ht3) Antagonists, A04aa	4	(0.2)	7	(0.4)	11	(0.3)
Ondansetron	3	(0.2)	6	(0.3)	9	(0.2)
Ondansetron Hydrochloride	1	(0.1)	0		1	(0.0)
Ramosetron Hydrochloride	0		1	(0.1)	1	(0.0)
Vitamin B1, Plain, A11da	7	(0.4)	4	(0.2)	11	(0.3)
Thiamine Hydrochloride	3	(0.2)	2	(0.1)	5	(0.1)
Benfotiamine	3	(0.2)	1	(0.1)	4	(0.1)
Fursultiamine	0		1	(0.1)	1	(0.0)
Fursultiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids, R03al	6	(0.3)	4	(0.2)	10	(0.3)
Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate	1	(0.1)	3	(0.2)	4	(0.1)
Olodaterol Hydrochloride; Tiotropium Bromide Monohydrate	3	(0.2)	0		3	(0.1)
Glycopyrronium Bromide; Indacaterol Maleate	2	(0.1)	0		2	(0.1)
Umeclidinium Bromide; Vilanterol Trifenatate	0		1	(0.1)	1	(0.0)
Carboxamide Derivatives, N03af01	4	(0.2)	6	(0.3)	10	(0.3)
Carbamazepine	4	(0.2)	6	(0.3)	10	(0.3)
Enzymes, C04af	7	(0.4)	3	(0.2)	10	(0.3)
Kallidinogenase	7	(0.4)	3	(0.2)	10	(0.3)
Heparin Group, B01ab	6	(0.3)	4	(0.2)	10	(0.3)
Sulodexide	4	(0.2)	2	(0.1)	6	(0.2)
Heparin	1	(0.1)	1	(0.1)	2	(0.1)
Enoxaparin Sodium	1	(0.1)	0		1	(0.0)
Tinzaparin Sodium	0		1	(0.1)	1	(0.0)
Imidazole And Triazole Derivatives, D01ac	7	(0.4)	3	(0.2)	10	(0.3)
Luliconazole	3	(0.2)	1	(0.1)	4	(0.1)
Efinaconazole	1	(0.1)	2	(0.1)	3	(0.1)
Betamethasone Dipropionate; Clotrimazole	1	(0.1)	0		1	(0.0)
Betamethasone; Clotrimazole	1	(0.1)	0		1	(0.0)
Hydrocortisone; Miconazole Nitrate	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Osmotically Acting Laxatives, A06ad	7	(0.4)	3	(0.2)	10	(0.3)
Macrogol 3350	6	(0.3)	1	(0.1)	7	(0.2)
Benzoic Acid; Lactitol	0		1	(0.1)	1	(0.0)
Lactulose	1	(0.1)	0		1	(0.0)
Macrogol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Sympathomimetics, R01ba	4	(0.2)	6	(0.3)	10	(0.3)
Pseudoephedrine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Pseudoephedrine	1	(0.1)	1	(0.1)	2	(0.1)
Atropa Belladonna Total Alkaloid Extract; Caffeine; Chlorphenamine Maleate; Dipotassium Glycyrrhizate; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Cetirizine Hydrochloride; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Ebastine; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Loratadine; Pseudoephedrine Sulfate	1	(0.1)	0		1	(0.0)
Pseudoephedrine Sulfate	0		1	(0.1)	1	(0.0)
Synthetic Anticholinergics, Esters With Tertiary Amino Group, A03aa	5	(0.3)	5	(0.3)	10	(0.3)
Dicycloverine	2	(0.1)	4	(0.2)	6	(0.2)
Mebeverine Hydrochloride	2	(0.1)	0		2	(0.1)
Dicycloverine Hydrochloride	0		1	(0.1)	1	(0.0)
Trimebutine Maleate	1	(0.1)	0		1	(0.0)
Antipropulsives, A07da	5	(0.3)	4	(0.2)	9	(0.2)
Loperamide Hydrochloride	4	(0.2)	2	(0.1)	6	(0.2)
Loperamide	0		2	(0.1)	2	(0.1)
Atropine Sulfate; Diphenoxylate Hydrochloride	1	(0.1)	0		1	(0.0)
Eluxadoline	1	(0.1)	0		1	(0.0)
Enzyme Preparations, A09aa	5	(0.3)	4	(0.2)	9	(0.2)
Pancreatin	3	(0.2)	3	(0.2)	6	(0.2)
Pancrelipase	1	(0.1)	1	(0.1)	2	(0.1)
Duodenum Siccum; Pancreatin	1	(0.1)	0		1	(0.0)
Hydrazinophthalazine Derivatives, C02db	3	(0.2)	6	(0.3)	9	(0.2)
Hydralazine	1	(0.1)	6	(0.3)	7	(0.2)
Dihydralazine Sulfate	1	(0.1)	0		1	(0.0)
Hydralazine Hydrochloride	1	(0.1)	0		1	(0.0)
Selective Immunosuppressants, L04aa	3	(0.2)	6	(0.3)	9	(0.2)
Mycophenolate Mofetil	2	(0.1)	3	(0.2)	5	(0.1)
Leflunomide	0		2	(0.1)	2	(0.1)
Mycophenolate Sodium	1	(0.1)	0		1	(0.0)
Vedolizumab	0		1	(0.1)	1	(0.0)
Tumor Necrosis Factor Alpha (Tnf-) Inhibitors, L04ab	5	(0.3)	4	(0.2)	9	(0.2)
Adalimumab	5	(0.3)	1	(0.1)	6	(0.2)
Etanercept	0		2	(0.1)	2	(0.1)
Golimumab	0		1	(0.1)	1	(0.0)
Aminosalicylic Acid And Similar Agents, A07ec	2	(0.1)	6	(0.3)	8	(0.2)
Mesalazine	2	(0.1)	6	(0.3)	8	(0.2)
Carbamic Acid Esters, M03ba	3	(0.2)	5	(0.3)	8	(0.2)
Methocarbamol	3	(0.2)	5	(0.3)	8	(0.2)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Iron In Combination With Folic Acid, B03ad	3	(0.2)	5	(0.3)	8	(0.2)
Ferrous Sulfate; Folic Acid	3	(0.2)	1	(0.1)	4	(0.1)
Ferrous Ascorbate; Folic Acid	0		2	(0.1)	2	(0.1)
Ferric Hydroxide Polymaltose Complex; Folic Acid	0		1	(0.1)	1	(0.0)
Ferrous Bisglycinate; Folic Acid	0		1	(0.1)	1	(0.0)
Low-Ceiling Diuretics And Potassium-Sparing Agents, C03ea	7	(0.4)	1	(0.1)	8	(0.2)
Hydrochlorothiazide; Triamterene	3	(0.2)	1	(0.1)	4	(0.1)
Amiloride Hydrochloride; Hydrochlorothiazide	3	(0.2)	0		3	(0.1)
Amiloride; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors, J05ab	6	(0.3)	2	(0.1)	8	(0.2)
Valaciclovir Hydrochloride	6	(0.3)	2	(0.1)	8	(0.2)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids, M01ax	4	(0.2)	4	(0.2)	8	(0.2)
Nabumetone	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Chondroitin Sulfate; Glucosamine Sulfate; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Calcium; Glucosamine	0		1	(0.1)	1	(0.0)
Chondroitin Sulfate; Glucosamine Hydrochloride; Hyaluronic Acid; Maltodextrin; Scutellaria Baicalensis Root; Senegalia Catechu Bark	0		1	(0.1)	1	(0.0)
Glucosamine Sulfate Potassium Chloride	0		1	(0.1)	1	(0.0)
Glucosamine Sulfate; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	1	(0.1)	0		1	(0.0)
Other Antipsoriatics For Topical Use, D05ax	6	(0.3)	2	(0.1)	8	(0.2)
Calcipotriol	4	(0.2)	0		4	(0.1)
Betamethasone Dipropionate; Calcipotriol Monohydrate	1	(0.1)	1	(0.1)	2	(0.1)
Betamethasone Dipropionate; Calcipotriol	0		1	(0.1)	1	(0.0)
Betamethasone; Calcipotriol	1	(0.1)	0		1	(0.0)
Other Drugs For Constipation, A06ax	2	(0.1)	6	(0.3)	8	(0.2)
Linaclotide	1	(0.1)	2	(0.1)	3	(0.1)
Lubiprostone	0		3	(0.2)	3	(0.1)
Potassium Bitartrate; Sodium Bicarbonate	1	(0.1)	0		1	(0.0)
Prucalopride	0		1	(0.1)	1	(0.0)
Aldose Reductase Inhibitors, A10xa	5	(0.3)	2	(0.1)	7	(0.2)
Epalrestat	5	(0.3)	2	(0.1)	7	(0.2)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations, C09dx	4	(0.2)	3	(0.2)	7	(0.2)
Amlodipine Besilate; Hydrochlorothiazide; Olmesartan Medoxomil	3	(0.2)	1	(0.1)	4	(0.1)
Sacubitril; Valsartan	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Hydrochlorothiazide; Valsartan	0		1	(0.1)	1	(0.0)
Antineovascularisation Agents, S01la	4	(0.2)	3	(0.2)	7	(0.2)
Aflibercept	2	(0.1)	2	(0.1)	4	(0.1)
Bevacizumab	1	(0.1)	1	(0.1)	2	(0.1)
Ranibizumab	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Combinations Of Oral Blood Glucose Lowering Drugs, A10bd	3	(0.2)	4	(0.2)	7	(0.2)
Metformin Hydrochloride; Sitagliptin Phosphate Monohydrate	1	(0.1)	1	(0.1)	2	(0.1)
Metformin Hydrochloride; Vildagliptin	1	(0.1)	1	(0.1)	2	(0.1)
Glibenclamide; Metformin	1	(0.1)	0		1	(0.0)
Glimepiride; Metformin Hydrochloride	0		1	(0.1)	1	(0.0)
Metformin Hydrochloride; Pioglitazone Hydrochloride	0		1	(0.1)	1	(0.0)
Opium Alkaloids And Derivatives, R05da	3	(0.2)	4	(0.2)	7	(0.2)
Codeine	2	(0.1)	2	(0.1)	4	(0.1)
Chlorphenamine Maleate; Dihydrocodeine Phosphate; Methylephedrine Hydrochloride-Dl	0		1	(0.1)	1	(0.0)
Codeine Phosphate	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide	0		1	(0.1)	1	(0.0)
Preparations With No Effect On Uric Acid Metabolism, M04ac	2	(0.1)	5	(0.3)	7	(0.2)
Colchicine	2	(0.1)	5	(0.3)	7	(0.2)
Sulfur-Containing Imidazole Derivatives, H03bb	5	(0.3)	2	(0.1)	7	(0.2)
Thiamazole	5	(0.3)	2	(0.1)	7	(0.2)
Vitamin D Tablet, A11cc04	3	(0.2)	4	(0.2)	7	(0.2)
Calcitriol	3	(0.2)	4	(0.2)	7	(0.2)
Vitamins With Minerals, A11jb	3	(0.2)	4	(0.2)	7	(0.2)
Vitamins With Minerals	1	(0.1)	3	(0.2)	4	(0.1)
Biotin; Calcium Pantothenate; Centella Asiatica; Choline Bitartrate; Cyanocobalamin; Folic Acid; Inositol; Medicago Sativa; Nicotinamide; Panax Ginseng; Pyridoxine Hydrochloride; Riboflavin; Rosa Canina; Thiamine	1	(0.1)	0		1	(0.0)
Biotin; Calcium Pantothenate; Chromic Chloride; Colecalciferol; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Folic Acid; Manganese Sulfate; Nicotinamide; Phytomenadione; Potassium Iodide; Pyridoxine Hydrochlorid	1	(0.1)	0		1	(0.0)
Chromium Picolinate; Cyanocobalamin; Folic Acid; Nicotinamide; Pyridoxine Hydrochloride; Selenious Acid; Zinc Sulfate Monohydrate	0		1	(0.1)	1	(0.0)
Xanthines, R03da	3	(0.2)	4	(0.2)	7	(0.2)
Theophylline	3	(0.2)	4	(0.2)	7	(0.2)
Aromatase Inhibitors, L02bg	4	(0.2)	2	(0.1)	6	(0.2)
Anastrozole	2	(0.1)	1	(0.1)	3	(0.1)
Letrozole	2	(0.1)	1	(0.1)	3	(0.1)
Bile Acid Sequestrants, C10ac	4	(0.2)	2	(0.1)	6	(0.2)
Colestyramine	3	(0.2)	0		3	(0.1)
Colesevelam	0		1	(0.1)	1	(0.0)
Colestipol	0		1	(0.1)	1	(0.0)
Colestipol Hydrochloride	1	(0.1)	0		1	(0.0)
Fatty Acid Derivatives, N03ag	2	(0.1)	4	(0.2)	6	(0.2)
Valproate Sodium	0		4	(0.2)	4	(0.1)
Valproate Magnesium	1	(0.1)	0		1	(0.0)
Valproate Sodium; Valproic Acid	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Anti-Dementia Drugs, N06dx	3	(0.2)	3	(0.2)	6	(0.2)
Memantine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Apoaequorin	0		2	(0.1)	2	(0.1)
Apoaequorin; Colecalciferol	1	(0.1)	0		1	(0.0)
Other Drugs Affecting Bone Structure And Mineralization, M05bx	3	(0.2)	3	(0.2)	6	(0.2)
Denosumab	3	(0.2)	3	(0.2)	6	(0.2)
Other Emollients And Protectives, D02ax	5	(0.3)	1	(0.1)	6	(0.2)
Ammonium Lactate	2	(0.1)	1	(0.1)	3	(0.1)
Benzalkonium Chloride; Chlorhexidine Hydrochloride; Isopropyl Myristate; Paraffin, Liquid	2	(0.1)	0		2	(0.1)
Paraffin Soft; Paraffin, Liquid	1	(0.1)	0		1	(0.0)
Progestogens And Estrogens, Fixed Combinations, G03aa	3	(0.2)	3	(0.2)	6	(0.2)
Drospirenone; Ethinylestradiol Betadex Clathrate	1	(0.1)	1	(0.1)	2	(0.1)
Ethinylestradiol; Gestodene	1	(0.1)	1	(0.1)	2	(0.1)
Ethinylestradiol; Norelgestromin	0		1	(0.1)	1	(0.0)
Ethinylestradiol; Norgestimate	1	(0.1)	0		1	(0.0)
Pyrazolones, N02bb	2	(0.1)	4	(0.2)	6	(0.2)
Metamizole	1	(0.1)	2	(0.1)	3	(0.1)
Metamizole Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Tetracyclines, J01aa	4	(0.2)	2	(0.1)	6	(0.2)
Doxycycline	2	(0.1)	2	(0.1)	4	(0.1)
Doxycycline Hyclate	1	(0.1)	0		1	(0.0)
Doxycycline Monohydrate	1	(0.1)	0		1	(0.0)
Beta Blocking Agents And Calcium Channel Blockers, C07fb	2	(0.1)	3	(0.2)	5	(0.1)
Atenolol; Nitrendipine	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Bisoprolol Fumarate	0		1	(0.1)	1	(0.0)
Amlodipine Besilate; Carvedilol	1	(0.1)	0		1	(0.0)
Cilnidipine; Nebivolol	0		1	(0.1)	1	(0.0)
Nitrofuran Derivatives, J01xe	4	(0.2)	1	(0.1)	5	(0.1)
Nitrofurantoin	4	(0.2)	1	(0.1)	5	(0.1)
Other Antiglaucoma Preparations, S01ex	2	(0.1)	3	(0.2)	5	(0.1)
Ripasudil Hydrochloride Dihydrate	2	(0.1)	2	(0.1)	4	(0.1)
Netarsudil Mesilate	0		1	(0.1)	1	(0.0)
Other Mineral Products, A12cx	3	(0.2)	2	(0.1)	5	(0.1)
Chromium Picolinate	2	(0.1)	1	(0.1)	3	(0.1)
Boron	1	(0.1)	0		1	(0.0)
Chromium Amino Acid Chelate	0		1	(0.1)	1	(0.0)
Vanadium	1	(0.1)	0		1	(0.0)
Other Sclerosing Agents, C05bx	3	(0.2)	2	(0.1)	5	(0.1)
Calcium Dobesilate	3	(0.2)	2	(0.1)	5	(0.1)
Penicillins With Extended Spectrum, J01ca	3	(0.2)	2	(0.1)	5	(0.1)
Amoxicillin	3	(0.2)	2	(0.1)	5	(0.1)
Pregnen (4) Derivatives, G03da	3	(0.2)	2	(0.1)	5	(0.1)
Progesterone	3	(0.2)	2	(0.1)	5	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Anticholinesterases, N06da	3	(0.2)	1	(0.1)	4	(0.1)
Rivastigmine	2	(0.1)	0		2	(0.1)
Donepezil	0		1	(0.1)	1	(0.0)
Donepezil Hydrochloride	1	(0.1)	0		1	(0.0)
Antiinflammatory Preparations, Non-Steroids For Topical Use, M02aa	3	(0.2)	1	(0.1)	4	(0.1)
Felbinac	2	(0.1)	1	(0.1)	3	(0.1)
Esflurbiprofen; Mentha Spp. Oil	1	(0.1)	0		1	(0.0)
Antivirals For Treatment Of Hiv Infections, Combinations, J05ar	3	(0.2)	1	(0.1)	4	(0.1)
Dolutegravir Sodium; Rilpivirine Hydrochloride	1	(0.1)	0		1	(0.0)
Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Alafenamide Fumarate	1	(0.1)	0		1	(0.0)
Emtricitabine; Tenofovir Disoproxil Fumarate	1	(0.1)	0		1	(0.0)
Lamivudine; Zidovudine	0		1	(0.1)	1	(0.0)
Benzamides, N05al	0		4	(0.2)	4	(0.1)
Levosulpiride	0		2	(0.1)	2	(0.1)
Amisulpride	0		1	(0.1)	1	(0.0)
Tiapride	0		1	(0.1)	1	(0.0)
Beta Blocking Agents, Selective, And Thiazides, C07bb	2	(0.1)	2	(0.1)	4	(0.1)
Bisoprolol Fumarate; Hydrochlorothiazide	2	(0.1)	1	(0.1)	3	(0.1)
Hydrochlorothiazide; Metoprolol Succinate	0		1	(0.1)	1	(0.0)
Corticosteroids, Potent (Group Iii), D07ac	3	(0.2)	1	(0.1)	4	(0.1)
Diflorasone Diacetate	1	(0.1)	0		1	(0.0)
Diflucortolone Valerate	1	(0.1)	0		1	(0.0)
Fludroxycortide	1	(0.1)	0		1	(0.0)
Methylprednisolone Aceponate	0		1	(0.1)	1	(0.0)
Drugs Used In Nicotine Dependence, N07ba	2	(0.1)	2	(0.1)	4	(0.1)
Varenicline Tartrate	2	(0.1)	1	(0.1)	3	(0.1)
Nicotine	0		1	(0.1)	1	(0.0)
Epinephrine, C01ca24	0		4	(0.2)	4	(0.1)
Epinephrine	0		4	(0.2)	4	(0.1)
Expectorants, R05ca	2	(0.1)	2	(0.1)	4	(0.1)
Guaifenesin	2	(0.1)	2	(0.1)	4	(0.1)
Glucocorticoids, H02ab	2	(0.1)	2	(0.1)	4	(0.1)
Prednisone	1	(0.1)	1	(0.1)	2	(0.1)
Deflazacort	1	(0.1)	0		1	(0.0)
Prednisolone Valeroacetate	0		1	(0.1)	1	(0.0)
Iron In Other Combinations, B03ae	2	(0.1)	2	(0.1)	4	(0.1)
Ascorbic Acid; Cyanocobalamin; Folic Acid; Iron	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Cyanocobalamin; Folic Acid; Iron; Pyridoxine Hydrochloride	1	(0.1)	0		1	(0.0)
Folic Acid; Iron; Zinc Sulfate	0		1	(0.1)	1	(0.0)
Liver Therapy, A05ba	3	(0.2)	1	(0.1)	4	(0.1)
Choline	1	(0.1)	0		1	(0.0)
Dimethyl 4,4'-Biphenyldicarboxylate	0		1	(0.1)	1	(0.0)
Ornithine Aspartate	1	(0.1)	0		1	(0.0)
Phospholipids Soybean	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors, J05af	2	(0.1)	2	(0.1)	4	(0.1)
Emtricitabine	1	(0.1)	1	(0.1)	2	(0.1)
Entecavir	1	(0.1)	1	(0.1)	2	(0.1)
Tenofovir	0		1	(0.1)	1	(0.0)
Tenofovir Alafenamide	1	(0.1)	0		1	(0.0)
Other Drugs For Functional Gastrointestinal Disorders, A03ax	1	(0.1)	3	(0.2)	4	(0.1)
Aluminium Hydroxide-Magnesium Carbonate Gel; Dimeticone; Magnesium Hydroxide; Silicon Dioxide, Colloidal	0		1	(0.1)	1	(0.0)
Pinaverium	0		1	(0.1)	1	(0.0)
Pinaverium Bromide	0		1	(0.1)	1	(0.0)
Simeticone	1	(0.1)	0		1	(0.0)
Phosphodiesterase Inhibitors, C01ce	3	(0.2)	1	(0.1)	4	(0.1)
Milrinone	3	(0.2)	1	(0.1)	4	(0.1)
Preparations Increasing Uric Acid Excretion, M04ab	2	(0.1)	2	(0.1)	4	(0.1)
Benzbromarone	2	(0.1)	2	(0.1)	4	(0.1)
Soft Paraffin And Fat Products, D02ac	2	(0.1)	2	(0.1)	4	(0.1)
White Soft Paraffin	1	(0.1)	2	(0.1)	3	(0.1)
Isopropyl Myristate; Paraffin, Liquid	1	(0.1)	0		1	(0.0)
Amino Acids, Incl. Combinations With Polypeptides, V06dd	1	(0.1)	2	(0.1)	3	(0.1)
Aspartic Acid	1	(0.1)	2	(0.1)	3	(0.1)
Antiarrhythmics, Class Ib, C01bb02	1	(0.1)	2	(0.1)	3	(0.1)
Mexiletine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Bile Therapy, A05a	2	(0.1)	1	(0.1)	3	(0.1)
Timonacic	2	(0.1)	1	(0.1)	3	(0.1)
Bulk-Forming Laxatives, A06ac	1	(0.1)	2	(0.1)	3	(0.1)
Polycarbophil Calcium	1	(0.1)	2	(0.1)	3	(0.1)
Calcineurin Inhibitors, L04ad	2	(0.1)	1	(0.1)	3	(0.1)
Ciclosporin	2	(0.1)	1	(0.1)	3	(0.1)
Calcium Channel Blockers And Diuretics, C08ga	3	(0.2)	0		3	(0.1)
Amlodipine Besilate; Indapamide	3	(0.2)	0		3	(0.1)
Corticosteroids, Potent, Other Combinations, D07xc	1	(0.1)	2	(0.1)	3	(0.1)
Betamethasone Dipropionate; Salicylic Acid	1	(0.1)	1	(0.1)	2	(0.1)
Mometasone Furoate; Salicylic Acid	0		1	(0.1)	1	(0.0)
General Nutrients, V06	1	(0.1)	2	(0.1)	3	(0.1)
General Nutrients	1	(0.1)	2	(0.1)	3	(0.1)
Indole Derivatives, N05ae	2	(0.1)	1	(0.1)	3	(0.1)
Lurasidone Hydrochloride	2	(0.1)	0		2	(0.1)
Ziprasidone	0		1	(0.1)	1	(0.0)
Interleukin Inhibitors, L04ac	2	(0.1)	1	(0.1)	3	(0.1)
Guselkumab	1	(0.1)	0		1	(0.0)
Risankizumab	0		1	(0.1)	1	(0.0)
Secukinumab	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Iron Trivalent, Oral Preparations, B03ab	2	(0.1)	1	(0.1)	3	(0.1)
Ferric Hydroxide Polymaltose Complex	2	(0.1)	1	(0.1)	3	(0.1)
Monoamine Oxidase B Inhibitors, N04bd	2	(0.1)	1	(0.1)	3	(0.1)
Rasagiline Mesylate	1	(0.1)	1	(0.1)	2	(0.1)
Rasagiline	1	(0.1)	0		1	(0.0)
Multivitamins, Combinations, A11a	3	(0.2)	0		3	(0.1)
Multivitamins, Combinations	3	(0.2)	0		3	(0.1)
Other Antiallergics, S01gx	1	(0.1)	2	(0.1)	3	(0.1)
Acitazanolast	1	(0.1)	2	(0.1)	3	(0.1)
Other Capillary Stabilizing Agents, C05cx	3	(0.2)	0		3	(0.1)
Hesperidin	3	(0.2)	0		3	(0.1)
Other Peripheral Vasodilators, C04ax	1	(0.1)	2	(0.1)	3	(0.1)
Naftidrofuryl Oxalate	1	(0.1)	2	(0.1)	3	(0.1)
Other Systemic Hemostatics, B02bx	2	(0.1)	1	(0.1)	3	(0.1)
Carbazochrome Sodium Sulfonate	2	(0.1)	1	(0.1)	3	(0.1)
Ovulation Stimulants, Synthetic, G03gb	1	(0.1)	2	(0.1)	3	(0.1)
Clomifene Citrate	1	(0.1)	1	(0.1)	2	(0.1)
Clomifene	0		1	(0.1)	1	(0.0)
Pregnadien Derivatives, G03db	0		3	(0.2)	3	(0.1)
Dienogest	0		2	(0.1)	2	(0.1)
Dydrogesterone	0		1	(0.1)	1	(0.0)
Salicylic Acid And Derivatives, N02ba	1	(0.1)	2	(0.1)	3	(0.1)
Acetylsalicylic Acid; Calcium Carbonate	0		1	(0.1)	1	(0.0)
Salicylic Acid And Derivatives	0		1	(0.1)	1	(0.0)
Salsalate	1	(0.1)	0		1	(0.0)
Selective Estrogen Receptor Modulators, G03xc	1	(0.1)	2	(0.1)	3	(0.1)
Bazedoxifene Acetate	0		1	(0.1)	1	(0.0)
Raloxifene	0		1	(0.1)	1	(0.0)
Raloxifene Hydrochloride	1	(0.1)	0		1	(0.0)
Thiouracils, H03ba	3	(0.2)	0		3	(0.1)
Propylthiouracil	3	(0.2)	0		3	(0.1)
Adrenergic And Dopaminergic Agents, C01ca	1	(0.1)	1	(0.1)	2	(0.1)
Midodrine	1	(0.1)	1	(0.1)	2	(0.1)
Agents For Dermatitis, Excluding Corticosteroids, D11ah	1	(0.1)	1	(0.1)	2	(0.1)
Pimecrolimus	0		1	(0.1)	1	(0.0)
Tralokinumab	1	(0.1)	0		1	(0.0)
Antiandrogens, Plain, G03ha	1	(0.1)	1	(0.1)	2	(0.1)
Cyproterone	0		1	(0.1)	1	(0.0)
Cyproterone Acetate	1	(0.1)	0		1	(0.0)
Antidiarrheal Microorganisms, A07f	1	(0.1)	1	(0.1)	2	(0.1)
Antidiarrheal Microorganisms	1	(0.1)	1	(0.1)	2	(0.1)
Antihypertensives, C02	1	(0.1)	1	(0.1)	2	(0.1)
Antihypertensives	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Barbiturates And Derivatives, N03aa	2	(0.1)	0		2	(0.1)
Primidone	2	(0.1)	0		2	(0.1)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds, A03bb	2	(0.1)	0		2	(0.1)
Hyoscine Butylbromide	2	(0.1)	0		2	(0.1)
Butyrophenone Derivatives, N05ad	2	(0.1)	0		2	(0.1)
Haloperidol	2	(0.1)	0		2	(0.1)
Calcitonin Gene-Related Peptide (Cgrp) Antagonists, N02cd	2	(0.1)	0		2	(0.1)
Erenumab Aooe	2	(0.1)	0		2	(0.1)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds, A02ad	1	(0.1)	1	(0.1)	2	(0.1)
Aluminium Hydroxide Gel; Magnesium Hydroxide	1	(0.1)	0		1	(0.0)
Aluminium Hydroxide; Magnesium Hydroxide	0		1	(0.1)	1	(0.0)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives, J01ee	0		2	(0.1)	2	(0.1)
Sulfamethoxazole; Trimethoprim	0		2	(0.1)	2	(0.1)
Corticosteroids, Plain, S01ba	1	(0.1)	1	(0.1)	2	(0.1)
Loteprednol Etabonate	1	(0.1)	1	(0.1)	2	(0.1)
Dopa And Dopa Derivatives, N04ba	2	(0.1)	0		2	(0.1)
Benserazide Hydrochloride; Levodopa	1	(0.1)	0		1	(0.0)
Carbidopa	1	(0.1)	0		1	(0.0)
Levodopa	1	(0.1)	0		1	(0.0)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02b	0		2	(0.1)	2	(0.1)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	0		1	(0.1)	1	(0.0)
Teprenone	0		1	(0.1)	1	(0.0)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia, V03ae	2	(0.1)	0		2	(0.1)
Calcium Polystyrene Sulfonate	1	(0.1)	0		1	(0.0)
Sodium Polystyrene Sulfonate	1	(0.1)	0		1	(0.0)
High-Ceiling Diuretics And Potassium-Sparing Agents, C03eb	1	(0.1)	1	(0.1)	2	(0.1)
Eplerenone; Torasemide	0		1	(0.1)	1	(0.0)
Furosemide; Spironolactone	1	(0.1)	0		1	(0.0)
Methyldopa, C02ab	0		2	(0.1)	2	(0.1)
Methyldopa	0		2	(0.1)	2	(0.1)
Mucolytics, R05cb	1	(0.1)	1	(0.1)	2	(0.1)
Carbocisteine	1	(0.1)	0		1	(0.0)
L-Carbocisteine	0		1	(0.1)	1	(0.0)
Non-Nucleoside Reverse Transcriptase Inhibitors, J05ag	0		2	(0.1)	2	(0.1)
Efavirenz	0		1	(0.1)	1	(0.0)
Rilpivirine	0		1	(0.1)	1	(0.0)
Other Analgesics And Antipyretics, N02bg	1	(0.1)	1	(0.1)	2	(0.1)
Gabapentin; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Mirogabalin Besilate	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Cough Suppressants, R05db	1	(0.1)	1	(0.1)	2	(0.1)
Benzonatate	1	(0.1)	1	(0.1)	2	(0.1)
Other Drugs Used In Benign Prostatic Hypertrophy, G04cx	2	(0.1)	0		2	(0.1)
Cernitin Gbx	1	(0.1)	0		1	(0.0)
Cucurbita Pepo Seed; Epilobium Parviflorum; Lycopene; Pyridoxine Hydrochloride; Serenoa Repens; Urtica Dioica Leaf; Vitamin E Nos; Zinc	1	(0.1)	0		1	(0.0)
Other Hypnotics And Sedatives, N05cm	0		2	(0.1)	2	(0.1)
Lemborexant	0		1	(0.1)	1	(0.0)
Suvorexant	0		1	(0.1)	1	(0.0)
Other Nervous System Drugs, N07xx	2	(0.1)	0		2	(0.1)
Dextromethorphan Hydrobromide; Quinidine Sulfate	1	(0.1)	0		1	(0.0)
Fampridine	1	(0.1)	0		1	(0.0)
Other Nutrients, V06d	1	(0.1)	1	(0.1)	2	(0.1)
Omega-7 Fatty Acids Nos	0		1	(0.1)	1	(0.0)
Other Nutrients	1	(0.1)	0		1	(0.0)
Other Therapeutic Products, V03ax	1	(0.1)	1	(0.1)	2	(0.1)
Bee Pollen	1	(0.1)	0		1	(0.0)
Other Therapeutic Products	0		1	(0.1)	1	(0.0)
Phenothiazines With Aliphatic Side-Chain, N05aa	0		2	(0.1)	2	(0.1)
Levomepromazine	0		1	(0.1)	1	(0.0)
Levomepromazine Maleate	0		1	(0.1)	1	(0.0)
Phenylpiperidine Derivatives, N02ab	2	(0.1)	0		2	(0.1)
Fentanyl	2	(0.1)	0		2	(0.1)
Preparations With Salicylic Acid Derivatives, M02ac	2	(0.1)	0		2	(0.1)
Borneol; Camphor; Diphenhydramine; Glycol Salicylate; Menthol; Methyl Salicylate; Squalene; Thymol	1	(0.1)	0		1	(0.0)
Trolamine Salicylate	1	(0.1)	0		1	(0.0)
Sympathomimetics, Combinations Excl. Corticosteroids, R01ab	1	(0.1)	1	(0.1)	2	(0.1)
Benzethonium Chloride; Chlorphenamine Maleate; Lidocaine; Naphazoline Hydrochloride	1	(0.1)	0		1	(0.0)
Calcium Propionate; Naphazoline Nitrate	0		1	(0.1)	1	(0.0)
Synthetic Anticholinergics, Quaternary Ammonium Compounds, A03ab	1	(0.1)	1	(0.1)	2	(0.1)
Clidinium Bromide	0		1	(0.1)	1	(0.0)
Otilonium	1	(0.1)	0		1	(0.0)
Third-Generation Cephalosporins, J01dd	0		2	(0.1)	2	(0.1)
Cefdinir	0		2	(0.1)	2	(0.1)
Tonics, A13a	2	(0.1)	0		2	(0.1)
Dietary Supplement	2	(0.1)	0		2	(0.1)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamin B-Complex With Vitamin C, A11eb	0		2	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Nicotinic Acid; Pantothenic Acid; Pyridoxine Hydrochloride; Riboflavin; Thiamine	0		1	(0.1)	1	(0.0)
Vitamin B-Complex, Incl. Combinations, A11e	1	(0.1)	1	(0.1)	2	(0.1)
Vitamin B-Complex, Incl. Combinations	1	(0.1)	1	(0.1)	2	(0.1)
Vitamin K, B02ba	2	(0.1)	0		2	(0.1)
Vitamin K Nos	2	(0.1)	0		2	(0.1)
Amides, N01bb	1	(0.1)	0		1	(0.0)
Ropivacaine Hydrochloride	1	(0.1)	0		1	(0.0)
Amino Acids And Derivatives, A16aa	0		1	(0.1)	1	(0.0)
Carnitine Orotate	0		1	(0.1)	1	(0.0)
Analgesics, N02	0		1	(0.1)	1	(0.0)
Analgesics	0		1	(0.1)	1	(0.0)
Antacids With Sodium Bicarbonate, A02ah	0		1	(0.1)	1	(0.0)
Aluminium Hydroxide Gel, Dried; Calcium Carbonate; Lipase; Magnesium Carbonate; Sodium Bicarbonate	0		1	(0.1)	1	(0.0)
Antacids, Other Combinations, A02ax	1	(0.1)	0		1	(0.0)
Aluminium Silicate; Calcium Carbonate; Cinnamomum Spp. Bark; Citrus Deliciosa Peel; Diastase; Foeniculum Vulgare; Gentiana Lutea Root; Magnesium Carbonate; Myristica Fragrans; Picrasma Quassioides Wood; Sodium	1	(0.1)	0		1	(0.0)
Anti-Androgens, L02bb	0		1	(0.1)	1	(0.0)
Bicalutamide	0		1	(0.1)	1	(0.0)
Anti-Estrogens, L02ba	1	(0.1)	0		1	(0.0)
Tamoxifen Citrate	1	(0.1)	0		1	(0.0)
Antidepressants In Combination With Psycholeptics, N06ca	0		1	(0.1)	1	(0.0)
Flupentixol Dihydrochloride; Melitracen Hydrochloride	0		1	(0.1)	1	(0.0)
Antifungals For Topical Use, D01a	1	(0.1)	0		1	(0.0)
Liranaftate	1	(0.1)	0		1	(0.0)
Antiinfectives For Treatment Of Acne, D10af	0		1	(0.1)	1	(0.0)
Nadifloxacin	0		1	(0.1)	1	(0.0)
Antiinflammatory And Antirheumatic Products, Non-Steroids, M01a	0		1	(0.1)	1	(0.0)
Antiinflammatory And Antirheumatic Products, Non-Steroids	0		1	(0.1)	1	(0.0)
Antracen Derivatives, D05ac	1	(0.1)	0		1	(0.0)
Dithranol	1	(0.1)	0		1	(0.0)
Ascorbic Acid (Vitamin C), Combinations, A11gb	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Calcium; Zinc	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Barbiturates, Plain, N05ca	1	(0.1)	0		1	(0.0)
Butalbital	1	(0.1)	0		1	(0.0)
Bile And Liver Therapy, A05	1	(0.1)	0		1	(0.0)
Bicyclol	1	(0.1)	0		1	(0.0)
Blood Glucose Lowering Drugs, Excl. Insulins, A10b	0		1	(0.1)	1	(0.0)
Chromium Picolinate; Cinnamomum Verum Bark; Colecalciferol	0		1	(0.1)	1	(0.0)
Centrally Acting Antiobesity Products, A08aa	0		1	(0.1)	1	(0.0)
Phentermine	0		1	(0.1)	1	(0.0)
Charcoal Preparations, A07ba	1	(0.1)	0		1	(0.0)
Ast 120	1	(0.1)	0		1	(0.0)
Choline Esters, N07ab	0		1	(0.1)	1	(0.0)
Bethanechol Chloride	0		1	(0.1)	1	(0.0)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors, J01cr	0		1	(0.1)	1	(0.0)
Amoxicillin Trihydrate; Clavulanate Potassium	0		1	(0.1)	1	(0.0)
Combinations Of Vitamins, A11ja	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Dl-Alpha Tocopheryl Acetate; Fursultiamine; Hydroxocobalamin Acetate; Pyridoxal Phosphate; Riboflavin Tetrabutyrate	1	(0.1)	0		1	(0.0)
Corticosteroids And Antiinfectives In Combination, S01ca	0		1	(0.1)	1	(0.0)
Loteprednol Etabonate; Tobramycin	0		1	(0.1)	1	(0.0)
Corticosteroids, Moderately Potent, Combinations With Antiseptics, D07bb	0		1	(0.1)	1	(0.0)
Chlorocresol; Clobetasone Butyrate	0		1	(0.1)	1	(0.0)
Dantrolene And Derivatives, M03ca	0		1	(0.1)	1	(0.0)
Dantrolene Sodium	0		1	(0.1)	1	(0.0)
Drugs Used In Erectile Dysfunction, G04be	0		1	(0.1)	1	(0.0)
Alprostadil; Papaverine; Phentolamine	0		1	(0.1)	1	(0.0)
Emollients And Protectives, D02a	0		1	(0.1)	1	(0.0)
Omega-6 Fatty Acids	0		1	(0.1)	1	(0.0)
Enemas, A06ag	1	(0.1)	0		1	(0.0)
Sodium Citrate; Sodium Lauryl Sulfoacetate	1	(0.1)	0		1	(0.0)
Ethers Chemically Close To Antihistamines, N04ab	1	(0.1)	0		1	(0.0)
Orphenadrine Hydrochloride	1	(0.1)	0		1	(0.0)
Glycogenolytic Hormones, H04aa	0		1	(0.1)	1	(0.0)
Glucagon	0		1	(0.1)	1	(0.0)
Heparins Or Heparinoids For Topical Use, C05ba	1	(0.1)	0		1	(0.0)
Heparins Or Heparinoids For Topical Use	1	(0.1)	0		1	(0.0)
Hormonal Contraceptives For Systemic Use, G03a	1	(0.1)	0		1	(0.0)
Oral Contraceptive Nos	1	(0.1)	0		1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Immunoglobulins, J06b	1	(0.1)	0		1	(0.0)
Immunoglobulins Nos	1	(0.1)	0		1	(0.0)
Integrase Inhibitors, J05aj	1	(0.1)	0		1	(0.0)
Bictegravir	1	(0.1)	0		1	(0.0)
Interferons, L03ab	1	(0.1)	0		1	(0.0)
Interferon Beta-1a	1	(0.1)	0		1	(0.0)
Long-Acting Sulfonamides, J01ed	1	(0.1)	0		1	(0.0)
Sulfamethoxypyridazine	1	(0.1)	0		1	(0.0)
Macrolides, J01fa	1	(0.1)	0		1	(0.0)
Roxithromycin	1	(0.1)	0		1	(0.0)
Mineral Supplements, A12	0		1	(0.1)	1	(0.0)
Mineral Supplements	0		1	(0.1)	1	(0.0)
Monoamine Oxidase A Inhibitors, N06ag	1	(0.1)	0		1	(0.0)
Moclobemide	1	(0.1)	0		1	(0.0)
Ophthalmologicals, S01	0		1	(0.1)	1	(0.0)
Ophthalmologicals	0		1	(0.1)	1	(0.0)
Opioids In Combination With Antispasmodics, N02ag	1	(0.1)	0		1	(0.0)
Atropa Belladonna Extract; Caffeine; Papaver Somniferum Tincture; Paracetamol	1	(0.1)	0		1	(0.0)
Opium Derivatives And Expectorants, R05fa	0		1	(0.1)	1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin	0		1	(0.1)	1	(0.0)
Other Alimentary Tract And Metabolism Products, A16a	0		1	(0.1)	1	(0.0)
Clostridium Butyricum	0		1	(0.1)	1	(0.0)
Other Anti-Parathyroid Agents, H05bx	0		1	(0.1)	1	(0.0)
Cinacalcet	0		1	(0.1)	1	(0.0)
Other Antiemetics, A04ad	1	(0.1)	0		1	(0.0)
Difenidol Hydrochloride	1	(0.1)	0		1	(0.0)
Other Antifungals For Topical Use, D01ae	0		1	(0.1)	1	(0.0)
Naftifine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antiinflammatory/Antirheumatic Agents In Combination With Other Drugs, M01bx	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Boron; Boswellia Serrata; Chondroitin; Gelatine Hydrolysate; Glucosamine; Hyaluronic Acid; Manganese; Methylsulfonylmethane	1	(0.1)	0		1	(0.0)
Other Antimigraine Preparations, N02cx	0		1	(0.1)	1	(0.0)
Lomerizine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Cardiac Combination Products, C01ex	1	(0.1)	0		1	(0.0)
Other Cardiac Combination Products	1	(0.1)	0		1	(0.0)
Other Cicatrizants, D03ax	1	(0.1)	0		1	(0.0)
Cadexomer Iodine	1	(0.1)	0		1	(0.0)
Other Dermatologicals, D11ax	0		1	(0.1)	1	(0.0)
Paraffin, Liquid; Polyethylene Resin	0		1	(0.1)	1	(0.0)

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Concomitant medication at screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Estrogens, G03cx	0		1	(0.1)	1	(0.0)
Tibolone	0		1	(0.1)	1	(0.0)
Other Immunostimulants, L03ax	0		1	(0.1)	1	(0.0)
Transfer Factor	0		1	(0.1)	1	(0.0)
Other Mineral Supplements, A12c	0		1	(0.1)	1	(0.0)
Magnesium Oxide; Zinc Sulfate	0		1	(0.1)	1	(0.0)
Other Parasympathomimetics, N07ax	0		1	(0.1)	1	(0.0)
Choline Alfoscerate	0		1	(0.1)	1	(0.0)
Other Urologicals, G04bx	0		1	(0.1)	1	(0.0)
Alanine; Copper; Cucurbita Spp.; Glutamic Acid; Glycine; Serenoa Repens Fruit; Urtica Dioica Leaf; Zinc	0		1	(0.1)	1	(0.0)
Peripheral Opioid Receptor Antagonists, A06ah	0		1	(0.1)	1	(0.0)
Naloxegol Oxalate	0		1	(0.1)	1	(0.0)
Phenol And Derivatives, D08ae	1	(0.1)	0		1	(0.0)
Cresol; Zinc Oxide	1	(0.1)	0		1	(0.0)
Prostaglandins, C01ea	0		1	(0.1)	1	(0.0)
Alprostadil	0		1	(0.1)	1	(0.0)
Psychostimulants, Agents Used For Adhd And Nootropics, N06b	1	(0.1)	0		1	(0.0)
Coffea Arabica; Cyanocobalamin; Folic Acid; Phosphatidyl Serine; Pyridoxine Hydrochloride	1	(0.1)	0		1	(0.0)
Pyrimidine Analogues, L01bc	1	(0.1)	0		1	(0.0)
Fluorouracil	1	(0.1)	0		1	(0.0)
Retinoids For Treatment Of Psoriasis, D05bb	0		1	(0.1)	1	(0.0)
Acitretin	0		1	(0.1)	1	(0.0)
Second-Generation Cephalosporins, J01dc	0		1	(0.1)	1	(0.0)
Cefaclor	0		1	(0.1)	1	(0.0)
Silicone Products, D02aa	0		1	(0.1)	1	(0.0)
Dimeticone; Silicones Nos	0		1	(0.1)	1	(0.0)
Substituted Alkylamines, R06ab	1	(0.1)	0		1	(0.0)
Dexchlorpheniramine Maleate	1	(0.1)	0		1	(0.0)
Trimethoprim And Derivatives, J01ea	0		1	(0.1)	1	(0.0)
Trimethoprim	0		1	(0.1)	1	(0.0)
Viral Vaccines, J07b	0		1	(0.1)	1	(0.0)
Viral Vaccines	0		1	(0.1)	1	(0.0)
Vitamin B-Complex With Minerals, A11ec	1	(0.1)	0		1	(0.0)
Yeast Dried	1	(0.1)	0		1	(0.0)
Zinc Products, D02ab	1	(0.1)	0		1	(0.0)
Menthol; Zinc Oxide	1	(0.1)	0		1	(0.0)
Zinc, A12cb	0		1	(0.1)	1	(0.0)
Zinc Orotate	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.26 Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	2170		2170		4340	
All medications	1817	(83.7)	1828	(84.2)	3645	(84.0)
Insulins And Analogues For Injection, Long-Acting, A10ae	864	(39.8)	901	(41.5)	1765	(40.7)
Insulin Glargine	441	(20.3)	437	(20.1)	878	(20.2)
Insulin Degludec	389	(17.9)	435	(20.1)	824	(19.0)
Insulin Detemir	26	(1.2)	11	(0.5)	37	(0.8)
Insulin Glargine Biosimilar 1	10	(0.5)	19	(0.9)	29	(0.7)
Insulin Degludec; Liraglutide	1	(0.1)	8	(0.4)	9	(0.2)
Insulin Glargine; Lixisenatide	2	(0.1)	0		2	(0.1)
Other Viral Vaccines, J07bx	778	(35.9)	797	(36.7)	1575	(36.3)
Tozinameran	542	(25.0)	518	(23.9)	1060	(24.4)
Elasomeran	153	(7.0)	164	(7.6)	317	(7.3)
Covid-19 Vaccine Nrvv Ad (Chadox1 Ncov-19)	61	(2.8)	66	(3.0)	127	(2.9)
Covid-19 Vaccine	50	(2.3)	48	(2.2)	98	(2.3)
Covid-19 Vaccine Nrvv Ad26 (Gam-Covid-Vac)	26	(1.2)	39	(1.8)	65	(1.5)
Covid-19 Vaccine Inact (Vero)	15	(0.7)	9	(0.4)	24	(0.6)
Covid-19 Vaccine Inact (Vero) Hb02	2	(0.1)	14	(0.7)	16	(0.4)
Covid-19 Vaccine Inact (Vero) Cz02	5	(0.2)	4	(0.2)	9	(0.2)
Covid-19 Vaccine Nrvv Ad26 (Jnj 78436735)	3	(0.1)	3	(0.1)	6	(0.1)
Covid-19 Vaccine Inact W.virion Aydar-1	1	(0.1)	0		1	(0.0)
Covid-19 Vaccine Nrvv Ad5 (Gam-Covid-Vac)	1	(0.1)	0		1	(0.0)
Covid-19 Vaccine Prot. Subunit (Epivaccorona)	1	(0.1)	0		1	(0.0)
Mvc-Cov1901	0		1	(0.1)	1	(0.0)
Multiple Atc, 0	582	(26.8)	599	(27.6)	1181	(27.2)
Azithromycin	56	(2.6)	46	(2.1)	102	(2.4)
Lidocaine	35	(1.6)	35	(1.6)	70	(1.6)
Levofloxacin	33	(1.5)	36	(1.7)	69	(1.6)
Prednisone	26	(1.2)	29	(1.3)	55	(1.3)
Ciprofloxacin	33	(1.5)	21	(1.0)	54	(1.2)
Dexamethasone	29	(1.3)	22	(1.0)	51	(1.2)
Sodium Chloride	25	(1.1)	25	(1.1)	50	(1.1)
Ascorbic Acid	24	(1.1)	25	(1.1)	49	(1.1)
Acetylcysteine	20	(0.9)	18	(0.8)	38	(0.9)
Hyaluronate Sodium	15	(0.7)	19	(0.9)	34	(0.8)
Nimesulide	14	(0.7)	16	(0.7)	30	(0.7)
Mecobalamin	14	(0.7)	15	(0.7)	29	(0.7)
Methylprednisolone	14	(0.7)	15	(0.7)	29	(0.7)
Metronidazole	13	(0.6)	16	(0.7)	29	(0.7)
Fluconazole	11	(0.5)	17	(0.8)	28	(0.7)
Triamcinolone Acetonide	13	(0.6)	15	(0.7)	28	(0.7)
Chlorphenamine Maleate	7	(0.3)	18	(0.8)	25	(0.6)
Clindamycin	11	(0.5)	12	(0.6)	23	(0.5)
Clarithromycin	10	(0.5)	12	(0.6)	22	(0.5)
Clotrimazole	13	(0.6)	8	(0.4)	21	(0.5)
Mometasone Furoate	11	(0.5)	10	(0.5)	21	(0.5)
Ofloxacin	8	(0.4)	13	(0.6)	21	(0.5)
Cefuroxime	12	(0.6)	8	(0.4)	20	(0.5)
Ciprofloxacin Hydrochloride	7	(0.3)	13	(0.6)	20	(0.5)
Betamethasone Valerate; Gentamicin Sulfate	9	(0.4)	10	(0.5)	19	(0.4)
Budesonide	10	(0.5)	9	(0.4)	19	(0.4)
Gentamicin Sulfate	8	(0.4)	11	(0.5)	19	(0.4)
Lidocaine Hydrochloride	6	(0.3)	13	(0.6)	19	(0.4)
Dimeticone	8	(0.4)	10	(0.5)	18	(0.4)
Moxifloxacin Hydrochloride	6	(0.3)	12	(0.6)	18	(0.4)
Prednisolone	9	(0.4)	9	(0.4)	18	(0.4)
Ambroxol Hydrochloride	7	(0.3)	10	(0.5)	17	(0.4)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ambroxol	7	(0.3)	9	(0.4)	16	(0.4)
Caffeine	6	(0.3)	10	(0.5)	16	(0.4)
Hydrocortisone	9	(0.4)	7	(0.3)	16	(0.4)
Betamethasone	9	(0.4)	6	(0.3)	15	(0.3)
Fluorometholone	6	(0.3)	8	(0.4)	14	(0.3)
Metoclopramide	6	(0.3)	8	(0.4)	14	(0.3)
Cortisone	7	(0.3)	6	(0.3)	13	(0.3)
Morphine	5	(0.2)	8	(0.4)	13	(0.3)
Clobetasol Propionate	3	(0.1)	9	(0.4)	12	(0.3)
Iron	6	(0.3)	6	(0.3)	12	(0.3)
Ketoconazole	8	(0.4)	4	(0.2)	12	(0.3)
Multivitamins, Plain	8	(0.4)	4	(0.2)	12	(0.3)
Vancomycin	6	(0.3)	6	(0.3)	12	(0.3)
Aciclovir	4	(0.2)	7	(0.3)	11	(0.2)
Betamethasone Butyrate Propionate	5	(0.2)	6	(0.3)	11	(0.2)
Chlorhexidine Gluconate	6	(0.3)	5	(0.2)	11	(0.2)
Heparinoid	7	(0.3)	4	(0.2)	11	(0.2)
Acetazolamide	4	(0.2)	6	(0.3)	10	(0.2)
All Other Therapeutic Products	5	(0.2)	5	(0.2)	10	(0.2)
Benzydamine Hydrochloride	6	(0.3)	4	(0.2)	10	(0.2)
Betamethasone Sodium Phosphate	2	(0.1)	8	(0.4)	10	(0.2)
Fluticasone	3	(0.1)	7	(0.3)	10	(0.2)
Fluticasone Furoate	4	(0.2)	6	(0.3)	10	(0.2)
Glycyrrhiza Spp. Root; Paeonia Lactiflora Root	4	(0.2)	6	(0.3)	10	(0.2)
Meclozine	3	(0.1)	7	(0.3)	10	(0.2)
Oxymetazoline Hydrochloride	5	(0.2)	5	(0.2)	10	(0.2)
Sodium Bicarbonate	4	(0.2)	6	(0.3)	10	(0.2)
Terbinafine Hydrochloride	4	(0.2)	6	(0.3)	10	(0.2)
Betamethasone Valerate	4	(0.2)	5	(0.2)	9	(0.2)
Chlorphenamine	4	(0.2)	5	(0.2)	9	(0.2)
Difluprednate	5	(0.2)	4	(0.2)	9	(0.2)
Moxifloxacin	5	(0.2)	4	(0.2)	9	(0.2)
Pyridoxine	3	(0.1)	6	(0.3)	9	(0.2)
Pyridoxine Hydrochloride	4	(0.2)	5	(0.2)	9	(0.2)
Bupivacaine	2	(0.1)	6	(0.3)	8	(0.2)
Dexamethasone Sodium Phosphate	3	(0.1)	5	(0.2)	8	(0.2)
Dexpanthenol	4	(0.2)	4	(0.2)	8	(0.2)
Docusate Sodium	1	(0.1)	7	(0.3)	8	(0.2)
Hydrocortisone Butyrate	3	(0.1)	5	(0.2)	8	(0.2)
Methylprednisolone Acetate	1	(0.1)	7	(0.3)	8	(0.2)
Sulfamethoxazole	4	(0.2)	4	(0.2)	8	(0.2)
Zinc	5	(0.2)	3	(0.1)	8	(0.2)
Brimonidine Tartrate	4	(0.2)	3	(0.1)	7	(0.2)
Erythromycin	3	(0.1)	4	(0.2)	7	(0.2)
Interferon Alfa-2b	5	(0.2)	2	(0.1)	7	(0.2)
Magnesium Sulfate	2	(0.1)	5	(0.2)	7	(0.2)
Menthol	3	(0.1)	4	(0.2)	7	(0.2)
Oxybuprocaine Hydrochloride	2	(0.1)	5	(0.2)	7	(0.2)
Povidone-Iodine	4	(0.2)	3	(0.1)	7	(0.2)
Pronase	3	(0.1)	4	(0.2)	7	(0.2)
Xylometazoline Hydrochloride	2	(0.1)	5	(0.2)	7	(0.2)
Bepotastine Besilate	3	(0.1)	3	(0.1)	6	(0.1)
Cefuroxime Sodium	2	(0.1)	4	(0.2)	6	(0.1)
Dequalinium Chloride	4	(0.2)	2	(0.1)	6	(0.1)
Fusidic Acid	4	(0.2)	2	(0.1)	6	(0.1)
Lactobacillus Acidophilus	4	(0.2)	2	(0.1)	6	(0.1)
Methylethylpiridinol Succinate	2	(0.1)	4	(0.2)	6	(0.1)
Metoclopramide Hydrochloride	2	(0.1)	4	(0.2)	6	(0.1)
Rifaximin	2	(0.1)	4	(0.2)	6	(0.1)
Terbinafine	4	(0.2)	2	(0.1)	6	(0.1)
Tolperisone	4	(0.2)	2	(0.1)	6	(0.1)
Triamcinolone	3	(0.1)	3	(0.1)	6	(0.1)
Azelastine Hydrochloride	2	(0.1)	3	(0.1)	5	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Betamethasone Dipropionate; Betamethasone Sodium Phosphate	3	(0.1)	2	(0.1)	5	(0.1)
Calcifediol	1	(0.1)	4	(0.2)	5	(0.1)
Calcium Sulfate Dihydrate; Dryopteris Crassirhizoma Rhizome; Ephedra Spp. Herb; Forsythia Suspensa; Glycyrrhiza Spp. Root With Rhizome; Houttuynia Cordata Herb; Isatis Tinctoria Root; Lonicera Japonica Flowe	0		5	(0.2)	5	(0.1)
Clindamycin Phosphate	0		5	(0.2)	5	(0.1)
Formoterol	2	(0.1)	3	(0.1)	5	(0.1)
Gentamicin	1	(0.1)	4	(0.2)	5	(0.1)
Guaiazulene	2	(0.1)	3	(0.1)	5	(0.1)
Ivermectin	1	(0.1)	4	(0.2)	5	(0.1)
Macrogol	1	(0.1)	4	(0.2)	5	(0.1)
Mucopolysaccharide Polysulfuric Acid Ester	1	(0.1)	4	(0.2)	5	(0.1)
Mupirocin	2	(0.1)	3	(0.1)	5	(0.1)
Neomycin Sulfate	2	(0.1)	3	(0.1)	5	(0.1)
Nystatin	2	(0.1)	3	(0.1)	5	(0.1)
Pilocarpine Hydrochloride	4	(0.2)	1	(0.1)	5	(0.1)
Propylene Glycol	4	(0.2)	1	(0.1)	5	(0.1)
Saccharated Iron Oxide	3	(0.1)	2	(0.1)	5	(0.1)
Salmeterol	2	(0.1)	3	(0.1)	5	(0.1)
Sodium Gualenate Hydrate	1	(0.1)	4	(0.2)	5	(0.1)
Sucralfate	3	(0.1)	2	(0.1)	5	(0.1)
Sulfadiazine Silver	0		5	(0.2)	5	(0.1)
Vitamin B12 Nos	4	(0.2)	1	(0.1)	5	(0.1)
Xylometazoline	1	(0.1)	4	(0.2)	5	(0.1)
Zinc Oxide	1	(0.1)	4	(0.2)	5	(0.1)
Ademetionine	1	(0.1)	3	(0.1)	4	(0.1)
Alisma Orientale Tuber; Atractylodes Lancea Rhizome; Cinnamomum Cassia Bark; Polyporus Umbellatus Sclerotium; Poria Cocos Sclerotium	1	(0.1)	3	(0.1)	4	(0.1)
Amikacin Sulfate	2	(0.1)	2	(0.1)	4	(0.1)
Ampicillin	0		4	(0.2)	4	(0.1)
Atropine Sulfate	1	(0.1)	3	(0.1)	4	(0.1)
Beclometasone Dipropionate	2	(0.1)	2	(0.1)	4	(0.1)
Cannabidiol	1	(0.1)	3	(0.1)	4	(0.1)
Dimenhydrinate	2	(0.1)	2	(0.1)	4	(0.1)
Fluocinonide	4	(0.2)	0		4	(0.1)
Gatifloxacin	0		4	(0.2)	4	(0.1)
Hydrocortisone Acetate	3	(0.1)	1	(0.1)	4	(0.1)
Imidazolyl Ethanamide Pentandioic Acid	3	(0.1)	1	(0.1)	4	(0.1)
Lactobacillus Nos	1	(0.1)	3	(0.1)	4	(0.1)
Magnesium Aspartate; Potassium Aspartate	1	(0.1)	3	(0.1)	4	(0.1)
Miconazole	1	(0.1)	3	(0.1)	4	(0.1)
Minerals Nos; Vitamins Nos	3	(0.1)	1	(0.1)	4	(0.1)
Miramistin	1	(0.1)	3	(0.1)	4	(0.1)
Mometasone	2	(0.1)	2	(0.1)	4	(0.1)
Neomycin	2	(0.1)	2	(0.1)	4	(0.1)
Oxiglutatione	0		4	(0.2)	4	(0.1)
Oxygen	2	(0.1)	2	(0.1)	4	(0.1)
Penicillin Nos	3	(0.1)	1	(0.1)	4	(0.1)
Potassium Aspartate	1	(0.1)	3	(0.1)	4	(0.1)
Prochlorperazine	3	(0.1)	1	(0.1)	4	(0.1)
Sildenafil Citrate	3	(0.1)	1	(0.1)	4	(0.1)
Steroids	1	(0.1)	3	(0.1)	4	(0.1)
Terbutaline Sulfate	1	(0.1)	3	(0.1)	4	(0.1)
Urea	1	(0.1)	3	(0.1)	4	(0.1)
Vitamins Nos	2	(0.1)	2	(0.1)	4	(0.1)
Aconitum Spp. Processed Root; Asarum Spp. Root; Ephedra Spp. Herb	2	(0.1)	1	(0.1)	3	(0.1)
Antibiotics	1	(0.1)	2	(0.1)	3	(0.1)
Asarum Spp. Root; Cinnamomum Cassia Bark;	2	(0.1)	1	(0.1)	3	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Pinellia Ternata Tuber; Schisandra Chinensis Fruit; Zingiber Officinale Rhizome						
Ascorbic Acid; Ferrous Sulfate	1	(0.1)	2	(0.1)	3	(0.1)
Benzocaine	3	(0.1)	0		3	(0.1)
Benzodiazepine Derivatives	0		3	(0.1)	3	(0.1)
Benzydamine	0		3	(0.1)	3	(0.1)
Betamethasone Dipropionate	2	(0.1)	1	(0.1)	3	(0.1)
Blood, Calf, Deprot., Lmw Portion	1	(0.1)	2	(0.1)	3	(0.1)
Bupivacaine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Capsaicin	2	(0.1)	1	(0.1)	3	(0.1)
Cetylpyridinium Chloride	1	(0.1)	2	(0.1)	3	(0.1)
Charcoal, Activated	0		3	(0.1)	3	(0.1)
Chloramphenicol	1	(0.1)	2	(0.1)	3	(0.1)
Chlorhexidine	3	(0.1)	0		3	(0.1)
Ciclesonide	2	(0.1)	1	(0.1)	3	(0.1)
Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Pueraria Lobata Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	1	(0.1)	2	(0.1)	3	(0.1)
Clobetasol	3	(0.1)	0		3	(0.1)
Colistin; Erythromycin Lactobionate	1	(0.1)	2	(0.1)	3	(0.1)
Cromoglicate Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Desonide	3	(0.1)	0		3	(0.1)
Dimetindene Maleate	0		3	(0.1)	3	(0.1)
Doxylamine Succinate	1	(0.1)	2	(0.1)	3	(0.1)
Fluorescein Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Gentiana Lutea Root; Primula Spp. Flower; Rumex Spp. Herb; Sambucus Nigra Flower; Verbena Officinalis Herb	2	(0.1)	1	(0.1)	3	(0.1)
Hydroxychloroquine	2	(0.1)	1	(0.1)	3	(0.1)
Levofloxacin Hemihydrate	1	(0.1)	2	(0.1)	3	(0.1)
Levomenthol	1	(0.1)	2	(0.1)	3	(0.1)
Meldonium	1	(0.1)	2	(0.1)	3	(0.1)
Methyl Salicylate	1	(0.1)	2	(0.1)	3	(0.1)
Miconazole Nitrate	3	(0.1)	0		3	(0.1)
Naloxone Hydrochloride; Oxycodone Hydrochloride	3	(0.1)	0		3	(0.1)
Naloxone Hydrochloride; Tilidine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Norfloxacin	1	(0.1)	2	(0.1)	3	(0.1)
Ofloxacin; Ornidazole	2	(0.1)	1	(0.1)	3	(0.1)
Ornidazole	2	(0.1)	1	(0.1)	3	(0.1)
Pheniramine Maleate	1	(0.1)	2	(0.1)	3	(0.1)
Phenol	2	(0.1)	1	(0.1)	3	(0.1)
Plantago Ovata	1	(0.1)	2	(0.1)	3	(0.1)
Prednisolone Acetate	1	(0.1)	2	(0.1)	3	(0.1)
Promethazine	2	(0.1)	1	(0.1)	3	(0.1)
Sildenafil	3	(0.1)	0		3	(0.1)
Sodium Alginate	1	(0.1)	2	(0.1)	3	(0.1)
Sodium Citrate Acid	0		3	(0.1)	3	(0.1)
Tacrolimus	2	(0.1)	1	(0.1)	3	(0.1)
Tolperisone Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Albumin Human	0		2	(0.1)	2	(0.1)
Alclometasone Dipropionate	1	(0.1)	1	(0.1)	2	(0.1)
All Other Non-Therapeutic Products	1	(0.1)	1	(0.1)	2	(0.1)
Amantadine	2	(0.1)	0		2	(0.1)
Ammonium Chloride	2	(0.1)	0		2	(0.1)
Anesthetics, Local	1	(0.1)	1	(0.1)	2	(0.1)
Angelica Sinensis; Ligusticum Chuanxiong	0		2	(0.1)	2	(0.1)
Arctium Lappa Fruit; Cicada Slough; Ephedra Spp. Herb; Eriobotrya Japonica Leaf; Perilla Frutescens Fruit; Perilla Frutescens Leaf; Peucedanum Praeruptorum Root; Pheretima Spp.;	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Schisandra Chinensis Fruit						
Arnica Montana	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Zinc	0		2	(0.1)	2	(0.1)
Azelastine	1	(0.1)	1	(0.1)	2	(0.1)
Azithromycin Dihydrate	2	(0.1)	0		2	(0.1)
Bacillus Subtilis	2	(0.1)	0		2	(0.1)
Bacitracin; Neomycin; Polymyxin B	1	(0.1)	1	(0.1)	2	(0.1)
Baicalin; Buffalo Horn; Cholic Acid; Concha Margaritifera; Gardenia Jasminoides Fruit; Hyodeoxycholic Acid; Isatis Tinctoria Root; Lonicera Japonica Flower	0		2	(0.1)	2	(0.1)
Benzethonium Chloride	1	(0.1)	1	(0.1)	2	(0.1)
Berberine	0		2	(0.1)	2	(0.1)
Betamethasone Acetate; Betamethasone Sodium Phosphate	1	(0.1)	1	(0.1)	2	(0.1)
Betamethasone Dipropionate; Gentamicin Sulfate	1	(0.1)	1	(0.1)	2	(0.1)
Buprenorphine	2	(0.1)	0		2	(0.1)
Buprenorphine Hydrochloride	2	(0.1)	0		2	(0.1)
Calcium Phosphate	2	(0.1)	0		2	(0.1)
Camphor; Menthol; Methyl Salicylate	2	(0.1)	0		2	(0.1)
Carmellose	0		2	(0.1)	2	(0.1)
Carmellose Sodium	0		2	(0.1)	2	(0.1)
Casirivimab	1	(0.1)	1	(0.1)	2	(0.1)
Casirivimab; Imdevimab	1	(0.1)	1	(0.1)	2	(0.1)
Chondroitin Sulfate Sodium	0		2	(0.1)	2	(0.1)
Chondroitin Sulfate; Hyaluronate Sodium	0		2	(0.1)	2	(0.1)
Chymotrypsin; Trypsin	1	(0.1)	1	(0.1)	2	(0.1)
Ciclopirox Olamine	2	(0.1)	0		2	(0.1)
Ciprofloxacin; Fluocinolone Acetonide	0		2	(0.1)	2	(0.1)
Clioquinol	2	(0.1)	0		2	(0.1)
Collagen	1	(0.1)	1	(0.1)	2	(0.1)
Cortisone Acetate	0		2	(0.1)	2	(0.1)
Curcuma Longa Rhizome	2	(0.1)	0		2	(0.1)
Dexamethasone Palmitate	1	(0.1)	1	(0.1)	2	(0.1)
Dexamethasone; Gentamicin Sulfate	0		2	(0.1)	2	(0.1)
Dihydrocodeine	0		2	(0.1)	2	(0.1)
Dupilumab	1	(0.1)	1	(0.1)	2	(0.1)
Enoxolone	0		2	(0.1)	2	(0.1)
Ethanol	1	(0.1)	1	(0.1)	2	(0.1)
Etofenamate	0		2	(0.1)	2	(0.1)
Ferric Sodium Gluconate Complex	2	(0.1)	0		2	(0.1)
Fexofenadine Hydrochloride; Pseudoephedrine Hydrochloride	0		2	(0.1)	2	(0.1)
Flunarizine Dihydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Folinic Acid	2	(0.1)	0		2	(0.1)
Ginkgo Biloba Extract	0		2	(0.1)	2	(0.1)
Ginkgo Biloba Leaf Dry Extract	1	(0.1)	1	(0.1)	2	(0.1)
Glucosamine	1	(0.1)	1	(0.1)	2	(0.1)
Glycerol	1	(0.1)	1	(0.1)	2	(0.1)
Gramicidin; Polymyxin B Sulfate	2	(0.1)	0		2	(0.1)
Hedera Helix; Thymus Vulgaris	1	(0.1)	1	(0.1)	2	(0.1)
Homeopathics Nos	1	(0.1)	1	(0.1)	2	(0.1)
Hyaluronic Acid	2	(0.1)	0		2	(0.1)
Hydrocortisone Sodium Succinate	0		2	(0.1)	2	(0.1)
Hydrocortisone; Oxytetracycline	0		2	(0.1)	2	(0.1)
Hypericum Perforatum	0		2	(0.1)	2	(0.1)
Hypromellose	2	(0.1)	0		2	(0.1)
Imdevimab	1	(0.1)	1	(0.1)	2	(0.1)
Iron Dextran	2	(0.1)	0		2	(0.1)
Lamotrigine	0		2	(0.1)	2	(0.1)
Macrogol 400	2	(0.1)	0		2	(0.1)
Mannitol	0		2	(0.1)	2	(0.1)
Mephenoxalone	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Mepyramine Maleate	1	(0.1)	1	(0.1)	2	(0.1)
Methadone	2	(0.1)	0		2	(0.1)
Molnupiravir	1	(0.1)	1	(0.1)	2	(0.1)
Monascus Purpureus	0		2	(0.1)	2	(0.1)
Naloxone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Naphazoline Nitrate	1	(0.1)	1	(0.1)	2	(0.1)
Neostigmine	1	(0.1)	1	(0.1)	2	(0.1)
Other Respiratory System Products	1	(0.1)	1	(0.1)	2	(0.1)
Pectin	2	(0.1)	0		2	(0.1)
Pheniramine	1	(0.1)	1	(0.1)	2	(0.1)
Plantago Ovata Husk	1	(0.1)	1	(0.1)	2	(0.1)
Potassium	1	(0.1)	1	(0.1)	2	(0.1)
Potassium Phosphate Dibasic; Potassium Phosphate Monobasic	1	(0.1)	1	(0.1)	2	(0.1)
Promethazine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Retinol	1	(0.1)	1	(0.1)	2	(0.1)
Senna Alexandrina	1	(0.1)	1	(0.1)	2	(0.1)
Serenoa Repens	0		2	(0.1)	2	(0.1)
Sotrovimab	1	(0.1)	1	(0.1)	2	(0.1)
Tioconazole	2	(0.1)	0		2	(0.1)
Tobramycin	1	(0.1)	1	(0.1)	2	(0.1)
Vancomycin Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Vidarabine	0		2	(0.1)	2	(0.1)
Zinc Sulfate	0		2	(0.1)	2	(0.1)
Zingiber Officinale	0		2	(0.1)	2	(0.1)
Abrus Melanospermus Herb; Acanthopanax Gracilistylus Root Bark; Achyranthes Bidentata Root; Aconitum Carmichaelii Root Tuber; Aconitum Kusnezoffii Root Tuber; Adenosma Caeruleum Herb; Angelica Biserrata Roo	1	(0.1)	0		1	(0.0)
Abutilon Theophrasti Seed; Akebia Spp. Stem; Cynanchum Paniculatum Root With Rhizome; Dianthus Superbus Herb; Glechoma Longituba Herb; Glycyrrhiza Spp. Root With Rhizome; Lonicera Japonica Stem; Plantago Spp	0		1	(0.1)	1	(0.0)
Acetylcarnitine Hydrochloride	1	(0.1)	0		1	(0.0)
Acetylcysteine Sodium	1	(0.1)	0		1	(0.0)
Achyranthes Aspera; Chaenomeles Speciosa; Cibotium Barometz Rhizome; Clematis Chinensis Root With Rhizome; Codonopsis Javanica Root; Cullen Corylifolium Fruit; Curcuma Longa Rhizome; Epimedium Spp. Leaf; Ptya	0		1	(0.1)	1	(0.0)
Achyranthes Bidentata Root; Atractylodes Macrocephala, Rhizoma; Codonopsis Spp. Root; Glycyrrhiza Spp. Root With Rhizome; Ligusticum Chuanxiong Rhizome; Panax Notoginseng Root; Pheretima Spp.; Poria Cocos Sc	1	(0.1)	0		1	(0.0)
Aciclovir Sodium	0		1	(0.1)	1	(0.0)
Aconitum Carmichaelii Root Tuber; Aconitum Kusnezoffii Root Tuber; Phryma Leptostachya Herb; Plantago Spp. Herb; Saposhnikovia Divaricata Root; Schizonepeta Tenuifolia Herb; Sophora Flavescens Root	1	(0.1)	0		1	(0.0)
Aconitum Carmichaelii Root; Anemarrhena Asphodeloides Rhizome; Angelica Biserrata Root; Animal Bone Nos; Carthamus Tinctorius Flower; Cibotium Barometz Rhizome; Cinnamomum Cassia Twig; Clematis Spp. Root Wit	1	(0.1)	0		1	(0.0)
Aconitum Kusnezoffii Root Tuber; Acorus Calamus Rhizome; Asparagus Cochinchinensis Root Tuber; Borneol; Camphor; Curcuma Longa Rhizome; Euphorbia Pekinensis Root; Menthol; Methyl Salicylate; Polygonatum Odorat	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Aconitum Kusnezoffii Root Tuber; Angelica Sinensis Root; Boswellia Spp. Resin; Commiphora Myrrha Resin; Flying Squirrel Feces; Herbal Nos; Liquidambar Formosana Resin; Momordica Cochinchinensis Seed; Musk; Phe	1	(0.1)	0		1	(0.0)
Aconitum Napellus; Citrullus Colocynthis; Gelsemium Sempervirens; Pulsatilla Pratensis; Verbascum Densiflorum	0		1	(0.1)	1	(0.0)
Acorus Calamus Var. Angustatus Rhizome; Angelica Dahurica Root; Angelica Spp. Root; Cinnamomum Cassia Twig; Ephedra Spp. Stem; Ligusticum Chuanxiong Rhizome; Mentha Canadensis Herb; Notopterygium Spp. Root W	0		1	(0.1)	1	(0.0)
Adenophora Spp. Root; Andrographis Paniculata Herb; Elaeagnus Pungens; Ephedra Spp. Herb; Papaver Somniferum; Platycodon Grandiflorus Root; Pseudostellaria Heterophylla Root; Stemona Spp. Root; Vitex Negundo	1	(0.1)	0		1	(0.0)
Aesculus Hippocastanum	1	(0.1)	0		1	(0.0)
Aesculus Hippocastanum Extract	0		1	(0.1)	1	(0.0)
Aesculus Hippocastanum Seed	0		1	(0.1)	1	(0.0)
Alanine; Arginine; Aspartic Acid; Cysteine; Glutamic Acid; Glycine; Histidine; Isoleucine; Leucine; Lysine Acetate; Methionine; Phenylalanine; Proline; Serine; Threonine; Tryptophan, L-; Tyrosine; Valine	0		1	(0.1)	1	(0.0)
Alginic Acid; Silver	0		1	(0.1)	1	(0.0)
Alisma Orientale Tuber; Atractylodes Lancea Rhizome; Bupleurum Falcatum Root; Cinnamomum Cassia Bark; Glycyrrhiza Spp. Root; Panax Ginseng Root; Pinellia Ternata Tuber; Polyporus Umbellatus Sclerotium; Poria	1	(0.1)	0		1	(0.0)
Alisma Orientale Tuber; Cornus Officinalis Fruit; Dioscorea Spp. Rhizome; Paeonia X Suffruticosa Root Bark; Poria Cocos Sclerotium; Rehmannia Glutinosa Root	1	(0.1)	0		1	(0.0)
Allium Cepa; Betula Spp. Leaf; Citrus Spp. Oil; Elymus Repens; Equisetum Spp.; Levisticum Spp. Root; Mentha X Piperita Oil; Petroselinum Crispum; Pinus Sylvestris Oil; Polygonum Aviculare; Salvia Spp. Oil; Solid	0		1	(0.1)	1	(0.0)
Aloe Spp.	1	(0.1)	0		1	(0.0)
Aloe Vera; Asini Corii Colla; Atractylodes Macrocephala; Citrus Spp. Unripe Fruit; Fallopia Multiflora; Lycium Barbarum Fruit; Panax Ginseng; Senna Tora Seed	0		1	(0.1)	1	(0.0)
Althaea Officinalis Extract; Sodium Bicarbonate	0		1	(0.1)	1	(0.0)
Althaea Officinalis; Calendula Officinalis; Glycyrrhiza Glabra	1	(0.1)	0		1	(0.0)
Aluminium Acetotartrate	0		1	(0.1)	1	(0.0)
Aluminium Silicate	1	(0.1)	0		1	(0.0)
Amantadine Hydrochloride	0		1	(0.1)	1	(0.0)
Amino Acids [Umbrella Term]	1	(0.1)	0		1	(0.0)
Amomum Spp. Fruit; Atractylodes Macrocephala, Rhizoma; Coix Lacryma-Jobi Subsp. Ma-Yuen Kernel; Dioscorea Oppositifolia Rhizome; Glycyrrhiza Spp. Root With Rhizome; Lablab Purpureus Seed; Nelumbo Nucifera S	0		1	(0.1)	1	(0.0)
Analgesics, Antipruritics, Astringents And Anti-Inflammatory Agents	0		1	(0.1)	1	(0.0)
Andrographis Paniculata; Bidens Pilosa Herb; Helicteres Angustifolia; Ilex Asprella Root; Isatis Tinctoria Leaf; Strobilanthes Cusia Root	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Andrographolide; Humic Acid; Spirulina Spp.	1	(0.1)	0		1	(0.0)
Anemarrhena Asphodeloides Rhizome; Angelica Acutiloba Root; Atractylodes Spp. Rhizome; Bupleurum Falcatum Root; Citrus Aurantium Peel; Cyperus Rotundus Rhizome; Fritillaria Thunbergii Bulb; Glycyrrhiza Spp.	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Astragalus Spp. Root; Atractylodes Spp. Rhizome; Bupleurum Falcatum Root; Cimicifuga Spp. Rhizome; Citrus Aurantium Peel; Glycyrrhiza Spp. Root; Panax Ginseng Root; Zingiber Officinal	0		1	(0.1)	1	(0.0)
Angelica Acutiloba Root; Astragalus Spp. Root; Cinnamomum Cassia Bark; Glycyrrhiza Spp. Root; Magnolia Spp. Bark; Paeonia Lactiflora Root; Panax Ginseng Root; Pinellia Ternata Tuber; Zanthoxylum Piperitum Per	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Astragalus Spp. Root; Atractylodes Lancea Rhizome; Citrus Aurantium Peel; Glycyrrhiza Spp. Root; Ophiopogon Japonicus Tuber; Panax Ginseng Root; Phellodendron Spp. Bark; Schisandra Ch	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Atractylodes Spp. Rhizome; Calcium Sulfate; Cnidium Officinale Rhizome; Ephedra Spp. Herb; Forsythia Spp. Fruit; Gardenia Jasminoides Fruit; Glycyrrhiza Spp. Root; Mentha Canadensis H	0		1	(0.1)	1	(0.0)
Angelica Acutiloba Root; Bupleurum Falcatum Root; Cimicifuga Spp. Rhizome; Glycyrrhiza Spp. Root; Rheum Spp. Rhizome; Scutellaria Baicalensis Root	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Gardenia Jasminoides Fruit; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Poria Cocos Sclerotium; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Angelica Archangelica Root; Carum Carvi Fruit; Chelidonium Majus Herb; Glycyrrhiza Glabra Root; Iberis Amara; Matricaria Recutita Flower; Melissa Officinalis Leaf; Mentha X Piperita Leaf; Silybum Marianum Fru	1	(0.1)	0		1	(0.0)
Angelica Dahurica Root; Astragalus Mongholicus Root; Chrysanthemum Indicum Flower; Glycyrrhiza Spp. Root With Rhizome; Ligusticum Chuanxiong Rhizome; Magnolia Spp. Flower Bud; Platycarya Strobilacea Infruct	1	(0.1)	0		1	(0.0)
Angelica Sinensis Root; Boswellia Sacra Bark Resin; Commiphora Myrrha Resin; Daemonorops Draco Fruit Resin; Drynaria Roosii Rhizome; Eupolyphaga Steleophaga; Pyrite; Rheum Spp. Root With Rhizome; Sodium Borat	0		1	(0.1)	1	(0.0)
Antiemetics And Antinauseants	1	(0.1)	0		1	(0.0)
Antihistamines	1	(0.1)	0		1	(0.0)
Armoracia Rusticana Root; Tropaeolum Majus	0		1	(0.1)	1	(0.0)
Artemisia Annua Herb; Bupleurum Chinense, Root; Forsythia Suspensa Fruit; Houttuynia Cordata Herb; Lonicera Japonica Flower Bud; Mentha Canadensis Herb; Platycodon Grandiflorus Root; Prunus Spp. Seed; Puerari	1	(0.1)	0		1	(0.0)
Artemisia Argyi Leaf	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Ferric Pyrophosphate	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Selenium; Zinc	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Aster Ageratoides Whole Plant; Firmiana Simplex Root; Metagentiana Rhodantha Whole Plant; Peucedanum Praeruptorum Root; Scleromitrion	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Diffusum Whole Plant; Scutellaria Baicalensis Root; Stemona Spp. Root Tu						
Atractylodes Lancea Extract; Citrus Aurantium; Coptis Chinensis Extract; Coptis Deltoidea Extract; Coptis Japonica Extract; Coptis Teeta Extract; Mallotus Japonicus Extract; Syzygium Aromaticum Tincture; Tetr	1	(0.1)	0		1	(0.0)
Atractylodes Macrocephala	0		1	(0.1)	1	(0.0)
Atropa Belladonna Extract; Papaver Somniferum Latex	0		1	(0.1)	1	(0.0)
Atropa Belladonna Herb Liquid Extract; Bletilla Striata; Corydalis Yanhusuo; Glycyrrhiza Spp. Root With Rhizome; Paeonia Lactiflora Root; Panax Notoginseng; Poria Cocos; Sepiae Endoconcha	0		1	(0.1)	1	(0.0)
Atropine	1	(0.1)	0		1	(0.0)
Atropine Sulfate Monohydrate	0		1	(0.1)	1	(0.0)
Aucklandia Costus; Buffalo Horn; Carthamus Tinctorius Flower; Cow Bezoar; Gardenia Jasminoides; Melia Azedarach Fruit; Mercury Sulfide; Musk; Nelumbo Nucifera Seed; Ophiopogon Japonicus Root Tuber; Pterocarpus	1	(0.1)	0		1	(0.0)
Bacillus Coagulans	1	(0.1)	0		1	(0.0)
Bacitracin Zinc; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Bacitracin Zinc; Neomycin Sulfate; Polymyxin B Sulfate	1	(0.1)	0		1	(0.0)
Bacteriophages	1	(0.1)	0		1	(0.0)
Benzalkonium Chloride	0		1	(0.1)	1	(0.0)
Benzalkonium Chloride; Eucalyptus Globulus Oil; Mentha X Piperita Oil; Menthol; Thymol	1	(0.1)	0		1	(0.0)
Benzathine Benzylpenicillin	0		1	(0.1)	1	(0.0)
Benzocaine; Menthol	0		1	(0.1)	1	(0.0)
Benzydamine Hydrochloride; Chlorhexidine Gluconate	1	(0.1)	0		1	(0.0)
Bepotastine	1	(0.1)	0		1	(0.0)
Berberine Hydrochloride; Borneol; Papaverine Hydrochloride; Rhus Spp. Galls; Sanguisorba Officinalis Root	1	(0.1)	0		1	(0.0)
Betamethasone Acetate	1	(0.1)	0		1	(0.0)
Betamethasone Sodium Phosphate; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Betamethasone Valerate; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Betula Spp. Leaf	1	(0.1)	0		1	(0.0)
Boric Acid	0		1	(0.1)	1	(0.0)
Borneol; Ligusticum Chuanxiong Rhizome	1	(0.1)	0		1	(0.0)
Boswellia Sacra Bark Resin; Carthamus Tinctorius Flower; Commiphora Myrrha Resin; Drynaria Roosii Rhizome; Periploca Sepium Root Bark; Pheretima Spp.; Stephania Tetrandra Root; Strychnos Nux-Vomica Seed	0		1	(0.1)	1	(0.0)
Botulinum Toxin Type A	1	(0.1)	0		1	(0.0)
Bovine Basic Fibroblast Growth Factor	0		1	(0.1)	1	(0.0)
Bromelains	1	(0.1)	0		1	(0.0)
Brompheniramine Maleate; Caffeine; Paracetamol	1	(0.1)	0		1	(0.0)
Buphenine	0		1	(0.1)	1	(0.0)
Bupleurum Falcatum Root; Calcium Sulfate; Glycyrrhiza Spp. Root; Panax Ginseng Root; Pinellia Ternata Tuber; Platycodon Grandiflorus Root; Scutellaria Baicalensis Root; Zingiber Officinale Rhizome; Ziziphus J	1	(0.1)	0		1	(0.0)
Cabergoline	0		1	(0.1)	1	(0.0)
Calcium Fluoride; Conium Maculatum; Hydrastis Canadensis; Thuja Occidentalis	0		1	(0.1)	1	(0.0)
Calcium Sulfate Dihydrate; Ephedra Spp. Stem;	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Glycyrrhiza Spp. Root With Rhizome; Papaver Somniferum Pericarp; Platycodon Grandiflorus Root; Prunus Spp. Seed; Raphanus Raphanistrum Subsp. Sativus Seed						
Camphor	0		1	(0.1)	1	(0.0)
Cannabis Sativa	0		1	(0.1)	1	(0.0)
Cannabis Sativa Fruit; Citrus Spp. Unripe Fruit; Magnolia Spp. Bark; Paeonia Lactiflora Root; Prunus Spp. Seed; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Capsicum Spp.; Gaultheria Procumbens; Mentha Arvensis	1	(0.1)	0		1	(0.0)
Carbomer	1	(0.1)	0		1	(0.0)
Carmellose Sodium; Gelatin; Pectin	1	(0.1)	0		1	(0.0)
Carmellose Sodium; Silver	0		1	(0.1)	1	(0.0)
Carpronium Chloride	0		1	(0.1)	1	(0.0)
Centaurium Erythraea; Levisticum Officinale Root Powder; Rosmarinus Officinalis Leaf Dry Extract	0		1	(0.1)	1	(0.0)
Centella Asiatica	1	(0.1)	0		1	(0.0)
Centipede; Forsythia Suspensa; Lonicera Japonica Flower; Phellodendron Chinense; Taraxacum Mongolicum Herb	0		1	(0.1)	1	(0.0)
Cetraria Islandica; Malva Sylvestris	1	(0.1)	0		1	(0.0)
Cetylpyridinium Chloride; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Chloramphenicol; Collagenase	1	(0.1)	0		1	(0.0)
Chloramphenicol; Dexamethasone; Polymyxin B Sulfate	0		1	(0.1)	1	(0.0)
Chlorphenamine Maleate; Ficus Microcarpa Leaf	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Paracetamol; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenoxamine Hydrochloride	1	(0.1)	0		1	(0.0)
Chondroitin Sulfate; Glucosamine Hydrochloride; Manganese Gluconate	1	(0.1)	0		1	(0.0)
Chondroitin Sulfate; Glucosamine Sulfate; Methylsulfonylmethane	0		1	(0.1)	1	(0.0)
Chondroitin; Glucosamine	1	(0.1)	0		1	(0.0)
Ciclopirox	1	(0.1)	0		1	(0.0)
Cinchocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Cinnamomum Camphora Oil; Foeniculum Vulgare; Rubia Tinctorum	1	(0.1)	0		1	(0.0)
Ciprofloxacin Hydrochloride; Dexamethasone	1	(0.1)	0		1	(0.0)
Ciprofloxacin Hydrochloride; Tinidazole	0		1	(0.1)	1	(0.0)
Citrus Aurantium	1	(0.1)	0		1	(0.0)
Clemastine	0		1	(0.1)	1	(0.0)
Clematis Spp. Extract; Prunella Vulgaris Extract; Trichosanthes Kirilowii Extract	0		1	(0.1)	1	(0.0)
Clioquinol; Flumetasone Pivalate	0		1	(0.1)	1	(0.0)
Clobetasone Butyrate	0		1	(0.1)	1	(0.0)
Colistimethate Sodium; Erythromycin Lactobionate	0		1	(0.1)	1	(0.0)
Colistin Sulfate	0		1	(0.1)	1	(0.0)
Colostrum	1	(0.1)	0		1	(0.0)
Contraceptives	0		1	(0.1)	1	(0.0)
Corticosteroids	1	(0.1)	0		1	(0.0)
Corydalis Bungeana Herb; Isatis Tinctoria Root; Scutellaria Baicalensis Root; Taraxacum Mongolicum Herb	0		1	(0.1)	1	(0.0)
Corydalis Bungeana; Isatis Indigotica; Scutellaria Baicalensis; Taraxacum Mongolicum	0		1	(0.1)	1	(0.0)
Creosote	1	(0.1)	0		1	(0.0)
Crotamiton; Hydrocortisone	0		1	(0.1)	1	(0.0)
Cucumis Melo Seed; Pig Bone	0		1	(0.1)	1	(0.0)
Cyclizine	0		1	(0.1)	1	(0.0)
Cysteine	1	(0.1)	0		1	(0.0)
Cysteine Hydrochloride; Glycyrrhizic Acid,	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ammonium Salt						
Dexamethasone Acetate	0		1	(0.1)	1	(0.0)
Dexamethasone; Moxifloxacin Hydrochloride	0		1	(0.1)	1	(0.0)
Dexamethasone; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Dexamethasone; Ofloxacin	1	(0.1)	0		1	(0.0)
Dexpanthenol; Retinol; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Dibekacin Sulfate	1	(0.1)	0		1	(0.0)
Dicycloverine Hydrochloride; Mefenamic Acid	0		1	(0.1)	1	(0.0)
Docusate	0		1	(0.1)	1	(0.0)
Doxepin	1	(0.1)	0		1	(0.0)
Doxylamine	1	(0.1)	0		1	(0.0)
Drynaria Roosii	1	(0.1)	0		1	(0.0)
Durapatite	1	(0.1)	0		1	(0.0)
Dyclonine Hydrochloride	1	(0.1)	0		1	(0.0)
Echinacea Purpurea	0		1	(0.1)	1	(0.0)
Ectoine	1	(0.1)	0		1	(0.0)
Electrolytes Nos	0		1	(0.1)	1	(0.0)
Ephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Estrone	1	(0.1)	0		1	(0.0)
Eucalyptus Spp. Oil; Mentha X Piperita Oil; Sulfanilamide; Sulfathiazole Sodium; Thymol	0		1	(0.1)	1	(0.0)
Fenoterol	1	(0.1)	0		1	(0.0)
Fenpiverinium; Metamizole; Pitofenone	1	(0.1)	0		1	(0.0)
Fenspiride	1	(0.1)	0		1	(0.0)
Fluorescein	1	(0.1)	0		1	(0.0)
Formoterol Fumarate Dihydrate	1	(0.1)	0		1	(0.0)
Framycetin	0		1	(0.1)	1	(0.0)
Fusidate Sodium	1	(0.1)	0		1	(0.0)
Gardenia Jasminoides Fruit; Isatis Tinctoria Root; Phellodendron Chinense Bark; Scaphium Affine Seed; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Gelatine Hydrolysate	0		1	(0.1)	1	(0.0)
Ginkgo Biloba Leaf Extract	1	(0.1)	0		1	(0.0)
Ginseng Nos; Minerals Nos; Vitamins Nos	0		1	(0.1)	1	(0.0)
Glucosamine Hydrochloride	1	(0.1)	0		1	(0.0)
Glycine	0		1	(0.1)	1	(0.0)
Glycine Max Seed Oil; Persea Americana Oil	1	(0.1)	0		1	(0.0)
Glycopyrronium	1	(0.1)	0		1	(0.0)
Glycopyrronium Bromide	0		1	(0.1)	1	(0.0)
Glycyrrhiza Glabra Root	0		1	(0.1)	1	(0.0)
Glycyrrhiza Glabra; Paeonia Lactiflora	1	(0.1)	0		1	(0.0)
Glycyrrhiza Spp. Root; Platycodon Grandiflorus Root	1	(0.1)	0		1	(0.0)
Glycyrrhiza Spp. Root; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Gramicidin S	0		1	(0.1)	1	(0.0)
Gramicidin; Neomycin Sulfate; Nystatin; Triamcinolone	1	(0.1)	0		1	(0.0)
Guaifenesin; Menthol	0		1	(0.1)	1	(0.0)
Hedera Helix Leaf	0		1	(0.1)	1	(0.0)
Hexetidine	0		1	(0.1)	1	(0.0)
Hydrocortisone Sodium Phosphate	0		1	(0.1)	1	(0.0)
Hydrocortisone Valerate	1	(0.1)	0		1	(0.0)
Hydroxocobalamin	0		1	(0.1)	1	(0.0)
Hydroxycarbamide	1	(0.1)	0		1	(0.0)
Hydroxyquinoline	1	(0.1)	0		1	(0.0)
Hylan G-F 20	1	(0.1)	0		1	(0.0)
Hyoscine	0		1	(0.1)	1	(0.0)
Ichthammol	0		1	(0.1)	1	(0.0)
Inosine	1	(0.1)	0		1	(0.0)
Iodine	1	(0.1)	0		1	(0.0)
Isoconazole	0		1	(0.1)	1	(0.0)
Isoconazole Nitrate	1	(0.1)	0		1	(0.0)
Ketotifen Fumarate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Lactobacillus Fermentum	1	(0.1)	0		1	(0.0)
Lactobacillus Reuteri	0		1	(0.1)	1	(0.0)
Lespedeza Capitata	1	(0.1)	0		1	(0.0)
Levomenthol; Primula Spp. Root; Thymus Spp. Herb	0		1	(0.1)	1	(0.0)
Lidocaine Hydrochloride Monohydrate	1	(0.1)	0		1	(0.0)
Lincomycin	1	(0.1)	0		1	(0.0)
Linoleic Acid	1	(0.1)	0		1	(0.0)
Liquidambar Formosana Fruit	0		1	(0.1)	1	(0.0)
Lysimachia Christiniae Herb	0		1	(0.1)	1	(0.0)
Lysozyme	0		1	(0.1)	1	(0.0)
Lysozyme Chloride	1	(0.1)	0		1	(0.0)
Macrogol 4000	1	(0.1)	0		1	(0.0)
Matricaria Recutita; Mercurius Solubilis Hahnemanni; Sulfur	0		1	(0.1)	1	(0.0)
Meldonium Dihydrate	0		1	(0.1)	1	(0.0)
Mentha X Piperita Oil	1	(0.1)	0		1	(0.0)
Mentha X Piperita Oil; Menthol; Sarcandra Glabra Herb	0		1	(0.1)	1	(0.0)
Menthol; Methyl Salicylate	0		1	(0.1)	1	(0.0)
Methylethylpiridinol	0		1	(0.1)	1	(0.0)
Methylprednisolone Sodium Succinate	0		1	(0.1)	1	(0.0)
Methylsulfonylmethane	1	(0.1)	0		1	(0.0)
Milnacipran Hydrochloride	1	(0.1)	0		1	(0.0)
Misoprostol	1	(0.1)	0		1	(0.0)
Mometasone Furoate Monohydrate	0		1	(0.1)	1	(0.0)
Momordica Charantia	1	(0.1)	0		1	(0.0)
Mupirocin Calcium	1	(0.1)	0		1	(0.0)
Muscle Relaxants	0		1	(0.1)	1	(0.0)
Myroxylon Balsamum Balsam	1	(0.1)	0		1	(0.0)
Naphazoline	0		1	(0.1)	1	(0.0)
Nicotinamide	1	(0.1)	0		1	(0.0)
Octenidine Hydrochloride	1	(0.1)	0		1	(0.0)
Ofloxacin Hydrochloride; Ornidazole	0		1	(0.1)	1	(0.0)
Omega-3 Nos	0		1	(0.1)	1	(0.0)
Orphenadrine	0		1	(0.1)	1	(0.0)
Other Antibacterials	0		1	(0.1)	1	(0.0)
Other Drugs For Disorders Of The Musculo-Skeletal System	0		1	(0.1)	1	(0.0)
Oxcarbazepine	1	(0.1)	0		1	(0.0)
Oxetacaine	0		1	(0.1)	1	(0.0)
Oxetacaine; Sucralfate	0		1	(0.1)	1	(0.0)
Oxiconazole Nitrate	1	(0.1)	0		1	(0.0)
Oxymetazoline	1	(0.1)	0		1	(0.0)
Paclitaxel	0		1	(0.1)	1	(0.0)
Palmidrol	0		1	(0.1)	1	(0.0)
Panax Quinquefolius Root	1	(0.1)	0		1	(0.0)
Papaver Somniferum; Platycodon Grandiflorus	1	(0.1)	0		1	(0.0)
Papaverine	1	(0.1)	0		1	(0.0)
Paraffin, Liquid; White Soft Paraffin	0		1	(0.1)	1	(0.0)
Passiflora Incarnata; Valeriana Officinalis	0		1	(0.1)	1	(0.0)
Periplaneta Americana	1	(0.1)	0		1	(0.0)
Phellodendron Amurense Bark	1	(0.1)	0		1	(0.0)
Phytomenadione	1	(0.1)	0		1	(0.0)
Pinus Spp. Tar; Sulfur	0		1	(0.1)	1	(0.0)
Piribedil	1	(0.1)	0		1	(0.0)
Polaprezinc	1	(0.1)	0		1	(0.0)
Polidocanol	0		1	(0.1)	1	(0.0)
Polihexanide; Undecylenamidopropyl Betaine	1	(0.1)	0		1	(0.0)
Polymyxin B Sulfate; Trimethoprim	0		1	(0.1)	1	(0.0)
Polymyxin B; Trimethoprim	1	(0.1)	0		1	(0.0)
Potassium Iodide	1	(0.1)	0		1	(0.0)
Potassium Phosphate Monobasic; Sodium Phosphate Dibasic; Sodium Phosphate Monobasic (Anhydrous)	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Pramocaine	0		1	(0.1)	1	(0.0)
Prednisolone Valeroacetate	1	(0.1)	0		1	(0.0)
Pregnenolone	1	(0.1)	0		1	(0.0)
Probiotics Nos	1	(0.1)	0		1	(0.0)
Procaine Hydrochloride	0		1	(0.1)	1	(0.0)
Prochlorperazine Maleate	1	(0.1)	0		1	(0.0)
Promelase	0		1	(0.1)	1	(0.0)
Propolis	1	(0.1)	0		1	(0.0)
Prunus Dulcis Oil	1	(0.1)	0		1	(0.0)
Pueraria Spp.	0		1	(0.1)	1	(0.0)
Quercus Salicina	0		1	(0.1)	1	(0.0)
Retinol Palmitate	1	(0.1)	0		1	(0.0)
Retinol; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Ribavirin	0		1	(0.1)	1	(0.0)
Riboflavin	1	(0.1)	0		1	(0.0)
Rifamycin Sodium	0		1	(0.1)	1	(0.0)
Ruscus Aculeatus	0		1	(0.1)	1	(0.0)
Rutoside	1	(0.1)	0		1	(0.0)
Sambucus Nigra	0		1	(0.1)	1	(0.0)
Sea Water	0		1	(0.1)	1	(0.0)
Secnidazole	0		1	(0.1)	1	(0.0)
Selenium	0		1	(0.1)	1	(0.0)
Senna Alexandrina Extract	0		1	(0.1)	1	(0.0)
Senna Alexandrina Glycoside Extract	1	(0.1)	0		1	(0.0)
Senna Spp.	0		1	(0.1)	1	(0.0)
Sertaconazole	1	(0.1)	0		1	(0.0)
Silicones Nos	1	(0.1)	0		1	(0.0)
Silver Protein	0		1	(0.1)	1	(0.0)
Silybum Marianum	1	(0.1)	0		1	(0.0)
Sodium Ascorbate	0		1	(0.1)	1	(0.0)
Sodium Bicarbonate; Sodium Gualenate Hydrate	0		1	(0.1)	1	(0.0)
Sodium Phosphate Dibasic	1	(0.1)	0		1	(0.0)
Sodium Phosphate Dibasic (Heptahydrate)	0		1	(0.1)	1	(0.0)
Sodium Phosphate Dibasic (Heptahydrate); Sodium Phosphate Monobasic (Monohydrate)	1	(0.1)	0		1	(0.0)
Sodium Phosphate Monobasic (Monohydrate)	0		1	(0.1)	1	(0.0)
Solidago Virgaurea Extract	1	(0.1)	0		1	(0.0)
Sorbitol	0		1	(0.1)	1	(0.0)
Strychnos Nux-Vomica Extract	1	(0.1)	0		1	(0.0)
Sulfasalazine	0		1	(0.1)	1	(0.0)
Sulpiride	0		1	(0.1)	1	(0.0)
Tetracaine Hydrochloride	1	(0.1)	0		1	(0.0)
Tetracycline	0		1	(0.1)	1	(0.0)
Tetracycline Hydrochloride	0		1	(0.1)	1	(0.0)
Tetryzoline	1	(0.1)	0		1	(0.0)
Tetryzoline Hydrochloride	1	(0.1)	0		1	(0.0)
Thiotriazoline	1	(0.1)	0		1	(0.0)
Tinidazole	1	(0.1)	0		1	(0.0)
Tocopherol	0		1	(0.1)	1	(0.0)
Tretinoin	0		1	(0.1)	1	(0.0)
Triamcinolone Acetonide Acetate	1	(0.1)	0		1	(0.0)
Triclosan	1	(0.1)	0		1	(0.0)
Triticum Aestivum	0		1	(0.1)	1	(0.0)
Trypsin	0		1	(0.1)	1	(0.0)
Tyrothricin	0		1	(0.1)	1	(0.0)
Urogastrone	0		1	(0.1)	1	(0.0)
Vaccinium Macrocarpon	0		1	(0.1)	1	(0.0)
Vascular Endothelial Growth Factor Inhibitors	0		1	(0.1)	1	(0.0)
Vitamin B Nos	1	(0.1)	0		1	(0.0)
Xysmalobium Undulatum Root	1	(0.1)	0		1	(0.0)
Zingiber Officinale Rhizome	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Insulin (Human), A10ab01	246	(11.3)	248	(11.4)	494	(11.4)
Insulin Aspart	145	(6.7)	147	(6.8)	292	(6.7)
Insulin Lispro	91	(4.2)	90	(4.2)	181	(4.2)
Insulin Human	6	(0.3)	8	(0.4)	14	(0.3)
Insulin	3	(0.1)	7	(0.3)	10	(0.2)
Insulin Porcine	1	(0.1)	3	(0.1)	4	(0.1)
Insulin Human; Insulin Human Injection, Isophane	3	(0.1)	0		3	(0.1)
Anilides, N02be	234	(10.8)	248	(11.4)	482	(11.1)
Paracetamol	205	(9.4)	227	(10.5)	432	(9.9)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Ephedrine Sulfate; Ethanol; Paracetamol	6	(0.3)	6	(0.3)	12	(0.3)
Caffeine; Paracetamol; Promethazine Methylene Disalicylate; Salicylamide	5	(0.2)	3	(0.1)	8	(0.2)
Dextromethorphan Hydrobromide; Guaifenesin; Paracetamol; Pseudoephedrine Hydrochloride	4	(0.2)	3	(0.1)	7	(0.2)
Ibuprofen; Paracetamol	2	(0.1)	4	(0.2)	6	(0.1)
Acetylsalicylic Acid; Caffeine; Paracetamol	0		3	(0.1)	3	(0.1)
Dextromethorphan Hydrobromide; Paracetamol; Phenylephrine Hydrochloride	0		3	(0.1)	3	(0.1)
Ascorbic Acid; Paracetamol; Pheniramine Maleate	0		2	(0.1)	2	(0.1)
Ascorbic Acid; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Caffeine; Paracetamol	0		2	(0.1)	2	(0.1)
Chlorphenamine Maleate; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan Hydrobromide; Guaifenesin; Paracetamol; Phenylephrine Hydrochloride	2	(0.1)	0		2	(0.1)
Dextromethorphan Hydrobromide; Paracetamol; Pseudoephedrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan; Guaifenesin; Paracetamol; Phenylephrine	2	(0.1)	0		2	(0.1)
Aceclofenac; Paracetamol	0		1	(0.1)	1	(0.0)
Aluminium Hydroxide Gel, Dried; Caffeine; Ibuprofen; Paracetamol	1	(0.1)	0		1	(0.0)
Amantadine Hydrochloride; Paracetamol	1	(0.1)	0		1	(0.0)
Ambroxol Hydrochloride; Chlorphenamine Maleate; Guaifenesin; Paracetamol; Phenylephrine Hydrochloride	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Caffeine; Chlorphenamine Maleate; Paracetamol	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Caffeine; Chlorphenamine Maleate; Paracetamol; Phenylephrine Hydrochloride; Salicylamide	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Caffeine; Paracetamol; Phenylephrine Hydrochloride; Terpin	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Chlorphenamine; Paracetamol	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Paracetamol	0		1	(0.1)	1	(0.0)
Bromhexine; Chlorphenamine; Guaifenesin; Paracetamol; Phenylephrine	0		1	(0.1)	1	(0.0)
Caffeine; Chlorphenamine Maleate; Cow Bezoar; Paracetamol	1	(0.1)	0		1	(0.0)
Caffeine; Chlorphenamine Maleate; Paracetamol	1	(0.1)	0		1	(0.0)
Caffeine; Diphenhydramine; Paracetamol; Phenylephrine	0		1	(0.1)	1	(0.0)
Caffeine; Mepyramine Maleate; Paracetamol	1	(0.1)	0		1	(0.0)
Caffeine; Paracetamol; Propyphenazone	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Cetirizine; Paracetamol; Phenylephrine	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dextromethorphan; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Paracetamol; Pseudoephedrine	0		1	(0.1)	1	(0.0)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Paracetamol; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine; Paracetamol	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Ephedrine Sulfate; Paracetamol	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin; Paracetamol	0		1	(0.1)	1	(0.0)
Dextromethorphan Hydrobromide; Paracetamol	1	(0.1)	0		1	(0.0)
Diclofenac; Paracetamol	0		1	(0.1)	1	(0.0)
Diphenhydramine Hydrochloride; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Diphenhydramine; Paracetamol; Phenylephrine	1	(0.1)	0		1	(0.0)
Mephenoxalone; Paracetamol	1	(0.1)	0		1	(0.0)
Paracetamol; Pheniramine Maleate; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Influenza Vaccines, J07bb	215	(9.9)	188	(8.7)	403	(9.3)
Influenza Vaccine	175	(8.1)	156	(7.2)	331	(7.6)
Influenza Vaccine Inact Split 4v	14	(0.7)	14	(0.7)	28	(0.7)
Influenza Vaccine Inact Sag 4v	12	(0.6)	10	(0.5)	22	(0.5)
Influenza Vaccine Inact Sag 3v	9	(0.4)	3	(0.1)	12	(0.3)
Influenza Vaccine Inact Split 3v	4	(0.2)	4	(0.2)	8	(0.2)
Influenza Vaccine Inact Split	0		1	(0.1)	1	(0.0)
Influenza Vaccine Rha 4v (Baculovirus)	1	(0.1)	0		1	(0.0)
Anticholinergics, S01fa	176	(8.1)	203	(9.3)	379	(8.7)
Phenylephrine Hydrochloride; Tropicamide	122	(5.6)	146	(6.7)	268	(6.2)
Tropicamide	52	(2.4)	55	(2.5)	107	(2.5)
Phenylephrine; Tropicamide	1	(0.1)	2	(0.1)	3	(0.1)
Cyclopentolate	1	(0.1)	1	(0.1)	2	(0.1)
Cyclopentolate Hydrochloride	0		1	(0.1)	1	(0.0)
Hydroxyamfetamine Hydrobromide; Tropicamide	1	(0.1)	0		1	(0.0)
Sulfonylureas, A10bb	191	(8.8)	182	(8.4)	373	(8.6)
Gliclazide	107	(4.9)	107	(4.9)	214	(4.9)
Glimepiride	40	(1.8)	51	(2.4)	91	(2.1)
Glipizide	29	(1.3)	13	(0.6)	42	(1.0)
Glibenclamide	16	(0.7)	11	(0.5)	27	(0.6)
Gliquidone	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Propionic Acid Derivatives, M01ae	167	(7.7)	181	(8.3)	348	(8.0)
Ibuprofen	84	(3.9)	89	(4.1)	173	(4.0)
Loxoprofen Sodium Dihydrate	28	(1.3)	28	(1.3)	56	(1.3)
Ketoprofen	22	(1.0)	13	(0.6)	35	(0.8)
Naproxen	16	(0.7)	16	(0.7)	32	(0.7)
Loxoprofen Sodium	13	(0.6)	13	(0.6)	26	(0.6)
Naproxen Sodium	9	(0.4)	15	(0.7)	24	(0.6)
Dexketoprofen	6	(0.3)	10	(0.5)	16	(0.4)
Flurbiprofen	4	(0.2)	6	(0.3)	10	(0.2)
Dexketoprofen Trometamol	4	(0.2)	5	(0.2)	9	(0.2)
Loxoprofen	1	(0.1)	5	(0.2)	6	(0.1)
Pranoprofen	2	(0.1)	2	(0.1)	4	(0.1)
Zaltoprofen	1	(0.1)	2	(0.1)	3	(0.1)
Apronal; Caffeine; Ibuprofen	0		2	(0.1)	2	(0.1)
Arginine Hydrochloride; Ibuprofen	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Ibuprofen; Pseudoephedrine Hydrochloride	2	(0.1)	0		2	(0.1)
Esflurbiprofen	1	(0.1)	1	(0.1)	2	(0.1)
Ibuprofen; Pseudoephedrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Ketoprofen Lysine	1	(0.1)	1	(0.1)	2	(0.1)
Aluminium Magnesium Silicate; Apronal; Caffeine; Loxoprofen Sodium Dihydrate	0		1	(0.1)	1	(0.0)
Benfotiamine; Caffeine; Chlorphenamine Maleate; Ibuprofen; Methylephedrine Hydrochloride-Dl; Riboflavin; Sulfogaiacol; Tipepidine Hibenzate	0		1	(0.1)	1	(0.0)
Chlorphenamine Maleate; Ibuprofen; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Dexibuprofen	1	(0.1)	0		1	(0.0)
Esomeprazole Magnesium; Naproxen	0		1	(0.1)	1	(0.0)
Pelubiprofen	0		1	(0.1)	1	(0.0)
Tiaprofenic Acid	1	(0.1)	0		1	(0.0)
Hmg Coa Reductase Inhibitors, C10aa	153	(7.0)	167	(7.7)	320	(7.4)
Atorvastatin	58	(2.7)	74	(3.4)	132	(3.0)
Rosuvastatin	43	(2.0)	36	(1.7)	79	(1.8)
Atorvastatin Calcium	21	(1.0)	28	(1.3)	49	(1.1)
Rosuvastatin Calcium	18	(0.8)	18	(0.8)	36	(0.8)
Simvastatin	8	(0.4)	9	(0.4)	17	(0.4)
Pravastatin	11	(0.5)	4	(0.2)	15	(0.3)
Pitavastatin Calcium	1	(0.1)	3	(0.1)	4	(0.1)
Pitavastatin	2	(0.1)	1	(0.1)	3	(0.1)
Pravastatin Sodium	2	(0.1)	0		2	(0.1)
Biguanides, A10ba	127	(5.8)	111	(5.1)	238	(5.5)
Metformin	80	(3.7)	82	(3.8)	162	(3.7)
Metformin Hydrochloride	47	(2.2)	29	(1.3)	76	(1.8)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Proton Pump Inhibitors, A02bc	100	(4.6)	109	(5.0)	209	(4.8)
Omeprazole	33	(1.5)	28	(1.3)	61	(1.4)
Pantoprazole Sodium Sesquihydrate	21	(1.0)	24	(1.1)	45	(1.0)
Pantoprazole	22	(1.0)	18	(0.8)	40	(0.9)
Lansoprazole	7	(0.3)	11	(0.5)	18	(0.4)
Esomeprazole Magnesium	8	(0.4)	8	(0.4)	16	(0.4)
Rabeprazole Sodium	3	(0.1)	10	(0.5)	13	(0.3)
Esomeprazole	6	(0.3)	5	(0.2)	11	(0.2)
Vonoprazan Fumarate	4	(0.2)	5	(0.2)	9	(0.2)
Dexlansoprazole	0		3	(0.1)	3	(0.1)
Domperidone; Pantoprazole	0		3	(0.1)	3	(0.1)
Domperidone; Pantoprazole Sodium Sesquihydrate	1	(0.1)	2	(0.1)	3	(0.1)
Rabeprazole	1	(0.1)	2	(0.1)	3	(0.1)
Domperidone; Rabeprazole	1	(0.1)	1	(0.1)	2	(0.1)
Domperidone; Esomeprazole	0		1	(0.1)	1	(0.0)
Domperidone; Omeprazole	1	(0.1)	0		1	(0.0)
Esomeprazole Magnesium Dihydrate	1	(0.1)	0		1	(0.0)
Esomeprazole Magnesium Trihydrate	1	(0.1)	0		1	(0.0)
Ilaprazole	1	(0.1)	0		1	(0.0)
Omeprazole Sodium	0		1	(0.1)	1	(0.0)
Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors, A10bk	98	(4.5)	92	(4.2)	190	(4.4)
Empagliflozin	52	(2.4)	43	(2.0)	95	(2.2)
Dapagliflozin	21	(1.0)	27	(1.2)	48	(1.1)
Dapagliflozin Propanediol Monohydrate	20	(0.9)	13	(0.6)	33	(0.8)
Canagliflozin	7	(0.3)	3	(0.1)	10	(0.2)
Ipragliflozin L-Proline	1	(0.1)	3	(0.1)	4	(0.1)
Ertugliflozin	0		2	(0.1)	2	(0.1)
Luseogliflozin	0		1	(0.1)	1	(0.0)
Glucagon-Like Peptide-1 (Glp-1) Analogues, A10bj	95	(4.4)	93	(4.3)	188	(4.3)
Semaglutide	57	(2.6)	54	(2.5)	111	(2.6)
Dulaglutide	27	(1.2)	34	(1.6)	61	(1.4)
Liraglutide	10	(0.5)	5	(0.2)	15	(0.3)
Exenatide	3	(0.1)	2	(0.1)	5	(0.1)
Lixisenatide	0		1	(0.1)	1	(0.0)
Acetic Acid Derivatives And Related Substances, M01ab	89	(4.1)	98	(4.5)	187	(4.3)
Diclofenac	28	(1.3)	29	(1.3)	57	(1.3)
Diclofenac Sodium	26	(1.2)	28	(1.3)	54	(1.2)
Ketorolac	8	(0.4)	8	(0.4)	16	(0.4)
Aceclofenac	8	(0.4)	6	(0.3)	14	(0.3)
Bromfenac Sodium	4	(0.2)	10	(0.5)	14	(0.3)
Ketorolac Tromethamine	5	(0.2)	9	(0.4)	14	(0.3)
Indometacin	4	(0.2)	8	(0.4)	12	(0.3)
Etodolac	5	(0.2)	3	(0.1)	8	(0.2)
Acemetacin	3	(0.1)	3	(0.1)	6	(0.1)
Diclofenac Diethylamine	0		2	(0.1)	2	(0.1)
Diclofenac Potassium	2	(0.1)	0		2	(0.1)
Diclofenac Sodium; Serrapeptase	1	(0.1)	1	(0.1)	2	(0.1)
Aceclofenac; Chymotrypsin; Paracetamol; Trypsin	1	(0.1)	0		1	(0.0)
Bromfenac	1	(0.1)	0		1	(0.0)
Diclofenac Epolamine	1	(0.1)	0		1	(0.0)
Diclofenac Sodium; Lidocaine	0		1	(0.1)	1	(0.0)
Diclofenac Sodium; Misoprostol	0		1	(0.1)	1	(0.0)
Indometacin Farnecyl Ester	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Angiotensin Ii Receptor Blockers (Arbs), Plain, C09ca	85	(3.9)	91	(4.2)	176	(4.1)
Losartan	29	(1.3)	29	(1.3)	58	(1.3)
Valsartan	14	(0.7)	22	(1.0)	36	(0.8)
Telmisartan	17	(0.8)	15	(0.7)	32	(0.7)
Candesartan	8	(0.4)	5	(0.2)	13	(0.3)
Irbesartan	4	(0.2)	7	(0.3)	11	(0.2)
Olmesartan	4	(0.2)	4	(0.2)	8	(0.2)
Candesartan Cilexetil	4	(0.2)	3	(0.1)	7	(0.2)
Losartan Potassium	2	(0.1)	4	(0.2)	6	(0.1)
Olmesartan Medoxomil	2	(0.1)	3	(0.1)	5	(0.1)
Azilsartan	3	(0.1)	1	(0.1)	4	(0.1)
Penicillins With Extended Spectrum, J01ca	91	(4.2)	85	(3.9)	176	(4.1)
Amoxicillin	82	(3.8)	66	(3.0)	148	(3.4)
Amoxicillin Trihydrate	9	(0.4)	18	(0.8)	27	(0.6)
Amoxicillin Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Carbenicillin Disodium	0		1	(0.1)	1	(0.0)
Pivmecillinam Hydrochloride	0		1	(0.1)	1	(0.0)
Platelet Aggregation Inhibitors Excl. Heparin, B01ac	74	(3.4)	75	(3.5)	149	(3.4)
Acetylsalicylic Acid	53	(2.4)	59	(2.7)	112	(2.6)
Clopidogrel	12	(0.6)	10	(0.5)	22	(0.5)
Clopidogrel Bisulfate	14	(0.7)	6	(0.3)	20	(0.5)
Ticagrelor	3	(0.1)	6	(0.3)	9	(0.2)
Prasugrel	3	(0.1)	3	(0.1)	6	(0.1)
Acetylsalicylic Acid; Magnesium Hydroxide	2	(0.1)	3	(0.1)	5	(0.1)
Prasugrel Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Acetylsalicylate Lysine	1	(0.1)	1	(0.1)	2	(0.1)
Acetylsalicylic Acid; Vonoprazan Fumarate	1	(0.1)	0		1	(0.0)
Dipyridamole	1	(0.1)	0		1	(0.0)
Salicylic Acid	1	(0.1)	0		1	(0.0)
Salicylic Acid; White Soft Paraffin	1	(0.1)	0		1	(0.0)
Tirofiban	1	(0.1)	0		1	(0.0)
Triflusal	0		1	(0.1)	1	(0.0)
Ace Inhibitors, Plain, C09aa	72	(3.3)	64	(3.0)	136	(3.1)
Ramipril	23	(1.1)	20	(0.9)	43	(1.0)
Lisinopril	20	(0.9)	14	(0.7)	34	(0.8)
Perindopril	13	(0.6)	11	(0.5)	24	(0.6)
Enalapril	7	(0.3)	8	(0.4)	15	(0.3)
Captopril	2	(0.1)	9	(0.4)	11	(0.2)
Enalapril Maleate	2	(0.1)	1	(0.1)	3	(0.1)
Fosinopril	1	(0.1)	1	(0.1)	2	(0.1)
Perindopril Arginine	0		2	(0.1)	2	(0.1)
Alacepril	1	(0.1)	0		1	(0.0)
Benazepril	1	(0.1)	0		1	(0.0)
Benazepril Hydrochloride	1	(0.1)	0		1	(0.0)
Imidapril Hydrochloride	0		1	(0.1)	1	(0.0)
Lisinopril Dihydrate	1	(0.1)	0		1	(0.0)
Perindopril Erbumine	1	(0.1)	0		1	(0.0)
Quinapril Hydrochloride	0		1	(0.1)	1	(0.0)
Trandolapril	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dihydropyridine Derivatives, C08ca	66	(3.0)	68	(3.1)	134	(3.1)
Amlodipine	42	(1.9)	36	(1.7)	78	(1.8)
Amlodipine Besilate	11	(0.5)	15	(0.7)	26	(0.6)
Nifedipine	5	(0.2)	7	(0.3)	12	(0.3)
Lercanidipine	1	(0.1)	5	(0.2)	6	(0.1)
Lercanidipine Hydrochloride	3	(0.1)	3	(0.1)	6	(0.1)
Cilnidipine	3	(0.1)	1	(0.1)	4	(0.1)
Lacidipine	1	(0.1)	2	(0.1)	3	(0.1)
Benidipine Hydrochloride	0		2	(0.1)	2	(0.1)
Nicardipine	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Maleate	1	(0.1)	0		1	(0.0)
Azelnidipine	1	(0.1)	0		1	(0.0)
Felodipine	1	(0.1)	0		1	(0.0)
Manidipine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antihistamines For Systemic Use, R06ax	68	(3.1)	63	(2.9)	131	(3.0)
Loratadine	18	(0.8)	24	(1.1)	42	(1.0)
Bilastine	10	(0.5)	10	(0.5)	20	(0.5)
Fexofenadine Hydrochloride	13	(0.6)	7	(0.3)	20	(0.5)
Olopatadine Hydrochloride	10	(0.5)	9	(0.4)	19	(0.4)
Desloratadine	8	(0.4)	8	(0.4)	16	(0.4)
Epinastine Hydrochloride	6	(0.3)	7	(0.3)	13	(0.3)
Rupatadine Fumarate	6	(0.3)	1	(0.1)	7	(0.2)
Fexofenadine	1	(0.1)	4	(0.2)	5	(0.1)
Epinastine	3	(0.1)	1	(0.1)	4	(0.1)
Ebastine	2	(0.1)	0		2	(0.1)
Olopatadine	1	(0.1)	1	(0.1)	2	(0.1)
Triprolidine Hydrochloride	0		2	(0.1)	2	(0.1)
Astemizole	0		1	(0.1)	1	(0.0)
Desloratadine Citrate Disodium	1	(0.1)	0		1	(0.0)
Loratadine Hydrochloride	0		1	(0.1)	1	(0.0)
Rupatadine	0		1	(0.1)	1	(0.0)
Beta Blocking Agents, Selective, C07ab	66	(3.0)	49	(2.3)	115	(2.6)
Metoprolol	18	(0.8)	15	(0.7)	33	(0.8)
Bisoprolol	13	(0.6)	12	(0.6)	25	(0.6)
Bisoprolol Fumarate	14	(0.7)	9	(0.4)	23	(0.5)
Metoprolol Succinate	10	(0.5)	2	(0.1)	12	(0.3)
Nebivolol	4	(0.2)	8	(0.4)	12	(0.3)
Metoprolol Tartrate	5	(0.2)	2	(0.1)	7	(0.2)
Nebivolol Hydrochloride	5	(0.2)	2	(0.1)	7	(0.2)
Atenolol	3	(0.1)	0		3	(0.1)
Betaxolol Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Beta Blocking Agents	1	(0.1)	0		1	(0.0)
Vitamin D And Analogues, A11cc	47	(2.2)	66	(3.0)	113	(2.6)
Colecalciferol	35	(1.6)	47	(2.2)	82	(1.9)
Vitamin D Nos	9	(0.4)	16	(0.7)	25	(0.6)
Ergocalciferol	2	(0.1)	2	(0.1)	4	(0.1)
Alfacalcidol	1	(0.1)	1	(0.1)	2	(0.1)
Colecalciferol-Cholesterin	1	(0.1)	1	(0.1)	2	(0.1)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Third-Generation Cephalosporins, J01dd	57	(2.6)	54	(2.5)	111	(2.6)
Ceftriaxone Sodium	14	(0.7)	8	(0.4)	22	(0.5)
Ceftriaxone	12	(0.6)	9	(0.4)	21	(0.5)
Cefdinir	13	(0.6)	5	(0.2)	18	(0.4)
Cefixime	9	(0.4)	5	(0.2)	14	(0.3)
Cefcapene Pivoxil Hydrochloride Hydrate	4	(0.2)	7	(0.3)	11	(0.2)
Cefcapene Pivoxil Hydrochloride	2	(0.1)	6	(0.3)	8	(0.2)
Cefpodoxime Proxetil	2	(0.1)	5	(0.2)	7	(0.2)
Cefditoren Pivoxil	3	(0.1)	2	(0.1)	5	(0.1)
Ceftazidime	1	(0.1)	3	(0.1)	4	(0.1)
Cefpodoxime	0		3	(0.1)	3	(0.1)
Ceftriaxone Sodium Sesquaterhydrate	1	(0.1)	2	(0.1)	3	(0.1)
Cefixime Trihydrate	1	(0.1)	1	(0.1)	2	(0.1)
Cefcapene Pivoxil	0		1	(0.1)	1	(0.0)
Cefoperazone; Sulbactam	1	(0.1)	0		1	(0.0)
Cefotaxime; Sulbactam	1	(0.1)	0		1	(0.0)
Cefpodoxime Proxetil; Clavulanate Potassium	0		1	(0.1)	1	(0.0)
Ceftizoxime Sodium	0		1	(0.1)	1	(0.0)
Ceftriaxone Sodium; Tazobactam Sodium	0		1	(0.1)	1	(0.0)
Insulins And Analogues For Injection, Intermediate-Acting, A10ac	49	(2.3)	60	(2.8)	109	(2.5)
Insulin Human Injection, Isophane	38	(1.8)	47	(2.2)	85	(2.0)
Isophane Insulin	11	(0.5)	10	(0.5)	21	(0.5)
Insulin Isophane Porcine	0		2	(0.1)	2	(0.1)
Insulin Lispro Protamine Suspension	0		2	(0.1)	2	(0.1)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors, J01cr	55	(2.5)	44	(2.0)	99	(2.3)
Amoxicillin; Clavulanic Acid	30	(1.4)	21	(1.0)	51	(1.2)
Amoxicillin Trihydrate; Clavulanate Potassium	14	(0.7)	12	(0.6)	26	(0.6)
Amoxicillin; Clavulanate Potassium	5	(0.2)	6	(0.3)	11	(0.2)
Piperacillin Sodium; Tazobactam Sodium	3	(0.1)	4	(0.2)	7	(0.2)
Amoxicillin Sodium; Clavulanate Potassium	3	(0.1)	2	(0.1)	5	(0.1)
Piperacillin; Tazobactam	1	(0.1)	1	(0.1)	2	(0.1)
Ampicillin; Sulbactam	0		1	(0.1)	1	(0.0)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	1	(0.1)	0		1	(0.0)
Heparin Group, B01ab	53	(2.4)	41	(1.9)	94	(2.2)
Enoxaparin Sodium	26	(1.2)	19	(0.9)	45	(1.0)
Heparin	10	(0.5)	10	(0.5)	20	(0.5)
Enoxaparin	9	(0.4)	7	(0.3)	16	(0.4)
Nadroparin Calcium	6	(0.3)	3	(0.1)	9	(0.2)
Heparin Sodium	2	(0.1)	1	(0.1)	3	(0.1)
Sulodexide	1	(0.1)	1	(0.1)	2	(0.1)
Certoparin Sodium	0		1	(0.1)	1	(0.0)
Heparin Porcine	1	(0.1)	0		1	(0.0)
Nadroparin	1	(0.1)	0		1	(0.0)
Tinzaparin Sodium	0		1	(0.1)	1	(0.0)
Phenylephrine, C01ca06	43	(2.0)	50	(2.3)	93	(2.1)
Phenylephrine Hydrochloride	33	(1.5)	41	(1.9)	74	(1.7)
Phenylephrine	8	(0.4)	9	(0.4)	17	(0.4)
Caffeine; Paracetamol; Phenylephrine	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Ibuprofen; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Paracetamol; Phenylephrine Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors, A10bh	41	(1.9)	48	(2.2)	89	(2.0)
Sitagliptin	11	(0.5)	11	(0.5)	22	(0.5)
Linagliptin	9	(0.4)	11	(0.5)	20	(0.5)
Vildagliptin	5	(0.2)	15	(0.7)	20	(0.5)
Sitagliptin Phosphate	12	(0.6)	7	(0.3)	19	(0.4)
Alogliptin	0		3	(0.1)	3	(0.1)
Teneligliptin	2	(0.1)	0		2	(0.1)
Gemigliptin	1	(0.1)	0		1	(0.0)
Saxagliptin	1	(0.1)	0		1	(0.0)
Saxagliptin Hydrochloride	1	(0.1)	0		1	(0.0)
Teneligliptin Hydrobromide	0		1	(0.1)	1	(0.0)
Teneligliptin Hydrobromide Hydrate	0		1	(0.1)	1	(0.0)
Beta-Lactamase Inhibitors, J01cg	36	(1.7)	38	(1.8)	74	(1.7)
Clavulanic Acid	34	(1.6)	27	(1.2)	61	(1.4)
Clavulanate Potassium	2	(0.1)	10	(0.5)	12	(0.3)
Tazobactam	0		1	(0.1)	1	(0.0)
Opium Alkaloids And Derivatives, R05da	35	(1.6)	38	(1.8)	73	(1.7)
Dextromethorphan Hydrobromide	10	(0.5)	13	(0.6)	23	(0.5)
Dextromethorphan	6	(0.3)	7	(0.3)	13	(0.3)
Codeine Phosphate	8	(0.4)	3	(0.1)	11	(0.2)
Codeine	4	(0.2)	5	(0.2)	9	(0.2)
Chlorphenamine Maleate; Dihydrocodeine Phosphate; Methylephedrine Hydrochloride-Dl	2	(0.1)	1	(0.1)	3	(0.1)
Dextromethorphan Hydrobromide; Promethazine Hydrochloride	0		3	(0.1)	3	(0.1)
Brompheniramine; Dextromethorphan; Pseudoephedrine	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Phenylephrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Codeine Phosphate; Promethazine Hydrochloride	2	(0.1)	0		2	(0.1)
Dextromethorphan Hydrobromide; Doxylamine Succinate	1	(0.1)	1	(0.1)	2	(0.1)
Dimemorfan Phosphate	0		2	(0.1)	2	(0.1)
Bromisoval; Dihydrocodeine Phosphate; Diprophylline; Methylephedrine Hydrochloride-Dl	0		1	(0.1)	1	(0.0)
Brompheniramine Maleate; Dextromethorphan Hydrobromide; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide	1	(0.1)	0		1	(0.0)
Chlorphenamine; Dextromethorphan	0		1	(0.1)	1	(0.0)
Codeine; Promethazine	1	(0.1)	0		1	(0.0)
Noscapine Hydrochloride	0		1	(0.1)	1	(0.0)
First-Generation Cephalosporins, J01db	32	(1.5)	38	(1.8)	70	(1.6)
Cefalexin	21	(1.0)	21	(1.0)	42	(1.0)
Cefazolin	4	(0.2)	8	(0.4)	12	(0.3)
Cefazolin Sodium	6	(0.3)	5	(0.2)	11	(0.2)
Cefadroxil	4	(0.2)	3	(0.1)	7	(0.2)
Cefazedone Sodium	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Glucocorticoids, H02ab	36	(1.7)	34	(1.6)	70	(1.6)
Prednisone	8	(0.4)	13	(0.6)	21	(0.5)
Dexamethasone	9	(0.4)	9	(0.4)	18	(0.4)
Methylprednisolone	6	(0.3)	5	(0.2)	11	(0.2)
Deflazacort	4	(0.2)	2	(0.1)	6	(0.1)
Methylprednisolone Acetate	2	(0.1)	3	(0.1)	5	(0.1)
Prednisolone	3	(0.1)	2	(0.1)	5	(0.1)
Cortisone	3	(0.1)	1	(0.1)	4	(0.1)
Dexamethasone Sodium Phosphate	1	(0.1)	2	(0.1)	3	(0.1)
Prednisolone Acetate	1	(0.1)	1	(0.1)	2	(0.1)
Prednisolone Valeroacetate	1	(0.1)	0		1	(0.0)
Fibrates, C10ab	38	(1.8)	31	(1.4)	69	(1.6)
Fenofibrate	21	(1.0)	18	(0.8)	39	(0.9)
Bezafibrate	15	(0.7)	9	(0.4)	24	(0.6)
Gemfibrozil	0		3	(0.1)	3	(0.1)
Fenofibric Acid	2	(0.1)	0		2	(0.1)
Ciprofibrate	0		1	(0.1)	1	(0.0)
Pregabalin, N03ax16	36	(1.7)	32	(1.5)	68	(1.6)
Pregabalin	35	(1.6)	32	(1.5)	67	(1.5)
Mecobalamin; Pregabalin	1	(0.1)	0		1	(0.0)
Coxibs, M01ah	35	(1.6)	32	(1.5)	67	(1.5)
Celecoxib	20	(0.9)	18	(0.8)	38	(0.9)
Etoricoxib	15	(0.7)	10	(0.5)	25	(0.6)
Parecoxib Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Imrecoxib	0		2	(0.1)	2	(0.1)
Parecoxib	0		1	(0.1)	1	(0.0)
Other Centrally Acting Agents, M03bx	30	(1.4)	34	(1.6)	64	(1.5)
Thiocolchicoside	6	(0.3)	11	(0.5)	17	(0.4)
Cyclobenzaprine	10	(0.5)	3	(0.1)	13	(0.3)
Tizanidine Hydrochloride	6	(0.3)	3	(0.1)	9	(0.2)
Cyclobenzaprine Hydrochloride	1	(0.1)	5	(0.2)	6	(0.1)
Tizanidine	1	(0.1)	5	(0.2)	6	(0.1)
Eperisone Hydrochloride	4	(0.2)	1	(0.1)	5	(0.1)
Fenyramidol Hydrochloride	2	(0.1)	3	(0.1)	5	(0.1)
Baclofen	0		4	(0.2)	4	(0.1)
Etodolac; Thiocolchicoside	0		1	(0.1)	1	(0.0)
Piperazine Derivatives, R06ae	31	(1.4)	33	(1.5)	64	(1.5)
Cetirizine Hydrochloride	14	(0.7)	10	(0.5)	24	(0.6)
Cetirizine	6	(0.3)	11	(0.5)	17	(0.4)
Levocetirizine Dihydrochloride	7	(0.3)	8	(0.4)	15	(0.3)
Levocetirizine	4	(0.2)	5	(0.2)	9	(0.2)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02bx	33	(1.5)	30	(1.4)	63	(1.4)
Rebamipide	25	(1.1)	23	(1.1)	48	(1.1)
Bismuth Subsalicylate	2	(0.1)	4	(0.2)	6	(0.1)
Troxipide	1	(0.1)	2	(0.1)	3	(0.1)
Calcium Carbonate; Sodium Alginate; Sodium Bicarbonate	2	(0.1)	0		2	(0.1)
Irsogladine Maleate	0		2	(0.1)	2	(0.1)
Ecabet Monosodium	1	(0.1)	0		1	(0.0)
Levoglutamide; Sodium Gualenate	1	(0.1)	0		1	(0.0)
Tripotassium Dicitratobismuthate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Opioids, N02ax	25	(1.1)	34	(1.6)	59	(1.4)
Tramadol	19	(0.9)	26	(1.2)	45	(1.0)
Tramadol Hydrochloride	5	(0.2)	8	(0.4)	13	(0.3)
Tapentadol	1	(0.1)	1	(0.1)	2	(0.1)
Tapentadol Hydrochloride	0		1	(0.1)	1	(0.0)
Gabapentin, N03ax12	29	(1.3)	26	(1.2)	55	(1.3)
Gabapentin	29	(1.3)	26	(1.2)	55	(1.3)
Sulfonamides, Plain, C03ca	29	(1.3)	26	(1.2)	55	(1.3)
Furosemide	22	(1.0)	23	(1.1)	45	(1.0)
Torasemide	4	(0.2)	2	(0.1)	6	(0.1)
Azosemide	3	(0.1)	0		3	(0.1)
Bumetanide	2	(0.1)	1	(0.1)	3	(0.1)
Natural Opium Alkaloids, N02aa	29	(1.3)	24	(1.1)	53	(1.2)
Hydrocodone	15	(0.7)	4	(0.2)	19	(0.4)
Oxycodone	7	(0.3)	8	(0.4)	15	(0.3)
Dihydrocodeine Phosphate	0		4	(0.2)	4	(0.1)
Morphine Sulfate	1	(0.1)	3	(0.1)	4	(0.1)
Oxycodone Hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Hydromorphone	2	(0.1)	1	(0.1)	3	(0.1)
Caffeine; Codeine Phosphate; Meprobamate; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Codeine Phosphate; Paracetamol; Pentobarbital Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Hydromorphone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Caffeine; Codeine; Meprobamate; Paracetamol	0		1	(0.1)	1	(0.0)
Opioids In Combination With Non-Opioid Analgesics, N02aj	30	(1.4)	22	(1.0)	52	(1.2)
Codeine Phosphate; Paracetamol	6	(0.3)	6	(0.3)	12	(0.3)
Paracetamol; Tramadol Hydrochloride	6	(0.3)	4	(0.2)	10	(0.2)
Hydrocodone Bitartrate; Paracetamol	6	(0.3)	2	(0.1)	8	(0.2)
Hydrocodone; Paracetamol	2	(0.1)	4	(0.2)	6	(0.1)
Codeine Phosphate; Ibuprofen; Paracetamol	3	(0.1)	0		3	(0.1)
Oxycodone Hydrochloride; Paracetamol	2	(0.1)	1	(0.1)	3	(0.1)
Caffeine; Carbinoxamine Maleate; Dihydrocodeine Phosphate; Guaifenesin; Lysozyme Chloride; Methylephedrine Hydrochloride-Dl; Paracetamol; Riboflavin; Sulbutiamine	1	(0.1)	1	(0.1)	2	(0.1)
Codeine; Paracetamol	2	(0.1)	0		2	(0.1)
Ambroxol Hydrochloride; Caffeine; Chlorphenamine Maleate; Dihydrocodeine Phosphate; Ibuprofen; Methylephedrine Hydrochloride-Dl	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Codeine Phosphate; Paracetamol	1	(0.1)	0		1	(0.0)
Benfotiamine; Caffeine; Clemastine Fumarate; Dihydrocodeine Phosphate; Methylephedrine Hydrochloride-Dl; Noscapine; Paracetamol; Sulfogaiacol	0		1	(0.1)	1	(0.0)
Caffeine; Chlorphenamine Maleate; Dihydrocodeine Phosphate; Glycyrrhiza Glabra Extract; Methylephedrine Hydrochloride-Dl; Paracetamol	0		1	(0.1)	1	(0.0)
Caffeine; Codeine Phosphate; Paracetamol	1	(0.1)	0		1	(0.0)
Codeine Phosphate Hemihydrate; Paracetamol	0		1	(0.1)	1	(0.0)
Dexketoprofen Trometamol; Tramadol Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamin B12 (Cyanocobalamin And Analogues), B03ba	25	(1.1)	27	(1.2)	52	(1.2)
Cyanocobalamin	21	(1.0)	22	(1.0)	43	(1.0)
Cyanocobalamin; Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	3	(0.1)	4	(0.1)
Cyanocobalamin-Tannin Complex	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate Dibasic; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Mononitrate	0		1	(0.1)	1	(0.0)
Cyanocobalamin; Lidocaine	1	(0.1)	0		1	(0.0)
Cyanocobalamin; Pyridoxine	0		1	(0.1)	1	(0.0)
Dexamethasone Sodium Phosphate; Hydroxocobalamin Acetate; Lidocaine Hydrochloride; Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Other Antivirals, J05ax	23	(1.1)	28	(1.3)	51	(1.2)
Umifenovir	10	(0.5)	18	(0.8)	28	(0.7)
Favipiravir	10	(0.5)	5	(0.2)	15	(0.3)
Inosine Pranobex	1	(0.1)	4	(0.2)	5	(0.1)
Bamlanivimab	1	(0.1)	1	(0.1)	2	(0.1)
Amenamevir	1	(0.1)	0		1	(0.0)
Bamlanivimab; Etesevimab	0		1	(0.1)	1	(0.0)
Casirivimab; Imdevimab	1	(0.1)	0		1	(0.0)
Tilorone	1	(0.1)	0		1	(0.0)
Unspecified Herbal And Traditional Medicine, V90	27	(1.2)	24	(1.1)	51	(1.2)
Traditional Medicine	11	(0.5)	8	(0.4)	19	(0.4)
Herbal Preparation	6	(0.3)	5	(0.2)	11	(0.2)
Unspecified Herbal	6	(0.3)	2	(0.1)	8	(0.2)
Unspecified Herbal And Traditional Medicine	0		3	(0.1)	3	(0.1)
Herbal Extract Nos	1	(0.1)	1	(0.1)	2	(0.1)
Aconitum Carmichaelii Root; Atractylodes Macrocephala, Rhizoma; Codonopsis Pilosula Root; Glycyrrhiza Uralensis Root With Rhizome; Zingiber Officinale Rhizome	0		1	(0.1)	1	(0.0)
Acorus Calamus Rhizome; Carum Carvi Fruit; Curcuma Longa Rhizome; Glycyrrhiza Spp. Root With Rhizome; Minerals Nos; Musk; Myristica Fragrans; Nardostachys Jatamansi Root With Rhizome; Tronae; Zanthoxylum Spp.	1	(0.1)	0		1	(0.0)
Akebia Quinata Stem; Alisma Orientale Rhizome; Angelica Sinensis Root; Bupleurum Chinense, Root; Gardenia Jasminoides Fruit; Gentiana Scabra Root; Glycyrrhiza Uralensis Root With Rhizome; Plantago Asiatica S	1	(0.1)	0		1	(0.0)
Alisma Orientale	1	(0.1)	0		1	(0.0)
Allium Sativum Bulb; Borneol; Crataegus Pinnatifida Fruit; Erigeron Breviscapus Herb; Ginkgo Biloba Leaf; Gynostemma Pentaphyllum Whole Plant; Panax Notoginseng Root; Salvia Miltiorrhiza Root	1	(0.1)	0		1	(0.0)
Angelica Sinensis Root; Codonopsis Pilosula Root; Glehnia Littoralis Root; Salvia Miltiorrhiza Root; Tinospora Sagittata Root Tuber	0		1	(0.1)	1	(0.0)
Arctium Lappa Fruit; Corydalis Bungeana Herb; Glycyrrhiza Uralensis Root With Rhizome; Lonicera Japonica Flower Bud; Platycodon Grandiflorus Root; Scrophularia Ningpoensis Root; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Astragalus Mongholicus Root; Crataegus Pinnatifida Fruit; Ligusticum Chuanxiong Rhizome; Ophiopogon Japonicus Root Tuber;	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Panax Ginseng Root; Salvia Miltiorrhiza Root; Schisandra Chinensis Fruit						
Bacopa Monnieri Herb; Camellia Sinensis Leaf; Curcuma Longa Rhizome; Silybum Marianum Seed; Withania Somnifera Root	0		1	(0.1)	1	(0.0)
Bupleurum Chinense, Root; Codonopsis Pilosula Root; Glycyrrhiza Uralensis Root With Rhizome; Pinellia Ternata Rhizome; Scutellaria Baicalensis Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	0		1	(0.1)	1	(0.0)
Chrysanthemum Indicum Flower; Ilex Asprella Root; Isatis Tinctoria Root; Lonicera Japonica Flower; Melicope Pteleifolia; Vitex Negundo	1	(0.1)	0		1	(0.0)
Chrysanthemum Indicum Inflorescence; Scutellaria Baicalensis Root; Taraxacum Mongolicum Herb; Viola Philippica Herb	0		1	(0.1)	1	(0.0)
Cinnamomum Verum Bark Oil; Citrus Limon Oil; Eucalyptus Radiata Oil; Rosmarinus Officinalis Oil; Syzygium Aromaticum Oil	1	(0.1)	0		1	(0.0)
Citrus Aurantium Fruit Peel; Crataegus Pinnatifida Fruit; Dioscorea Polystachya Rhizome; Hordeum Vulgare Sprout; Pseudostellaria Heterophylla Rhizome	1	(0.1)	0		1	(0.0)
Citrus Aurantium Fruit; Isodon Amethystoides; Panax Ginseng	1	(0.1)	0		1	(0.0)
Citrus Maxima Peel	0		1	(0.1)	1	(0.0)
Mentha Canadensis Oil	1	(0.1)	0		1	(0.0)
Phellodendron Spp.	1	(0.1)	0		1	(0.0)
Poria Cocos	0		1	(0.1)	1	(0.0)
Pueraria Spp. Root	0		1	(0.1)	1	(0.0)
Quercus Salicina Extract	0		1	(0.1)	1	(0.0)
Scutellaria Spp.	0		1	(0.1)	1	(0.0)
Sophora Flavescens Root; Trimethoprim	0		1	(0.1)	1	(0.0)
Traditional Chinese Medicine (Tcm) Decoction	1	(0.1)	0		1	(0.0)
Pyrazolones, N02bb	23	(1.1)	27	(1.2)	50	(1.1)
Metamizole Sodium	17	(0.8)	13	(0.6)	30	(0.7)
Metamizole	4	(0.2)	6	(0.3)	10	(0.2)
Metamizole Magnesium	1	(0.1)	3	(0.1)	4	(0.1)
Aminophenazone	0		3	(0.1)	3	(0.1)
Propyphenazone	1	(0.1)	2	(0.1)	3	(0.1)
Metamizole Sodium Monohydrate	0		1	(0.1)	1	(0.0)
Direct Factor Xa Inhibitors, B01af	29	(1.3)	20	(0.9)	49	(1.1)
Apixaban	12	(0.6)	12	(0.6)	24	(0.6)
Rivaroxaban	15	(0.7)	7	(0.3)	22	(0.5)
Edoxaban Tosilate	2	(0.1)	1	(0.1)	3	(0.1)
Mucolytics, R05cb	28	(1.3)	21	(1.0)	49	(1.1)
L-Carbocisteine	7	(0.3)	6	(0.3)	13	(0.3)
Carbocisteine	4	(0.2)	8	(0.4)	12	(0.3)
Erdosteine	6	(0.3)	5	(0.2)	11	(0.2)
Bromhexine Hydrochloride	7	(0.3)	2	(0.1)	9	(0.2)
Bromhexine	2	(0.1)	1	(0.1)	3	(0.1)
Acetylcysteine	1	(0.1)	0		1	(0.0)
Bromhexine Hydrochloride; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Lipid Modifying Agents, C10ax	24	(1.1)	24	(1.1)	48	(1.1)
Ezetimibe	16	(0.7)	13	(0.6)	29	(0.7)
Fish Oil	4	(0.2)	3	(0.1)	7	(0.2)
Omega-3-Acid Ethyl Ester	1	(0.1)	4	(0.2)	5	(0.1)
Evolocumab	2	(0.1)	1	(0.1)	3	(0.1)
Eicosapentaenoic Acid Ethyl Ester	0		2	(0.1)	2	(0.1)
Alirocumab	0		1	(0.1)	1	(0.0)
Dihydroquercetin	0		1	(0.1)	1	(0.0)
Linolenic Acid	1	(0.1)	0		1	(0.0)
Omega-3 Fatty Acids; Vitamin E Nos	0		1	(0.1)	1	(0.0)
Insulins And Analogues For Injection, Fast-Acting, A10ab	19	(0.9)	28	(1.3)	47	(1.1)
Insulin Glulisine	18	(0.8)	28	(1.3)	46	(1.1)
Insulin Lispro Aabc	1	(0.1)	0		1	(0.0)
Other Antidepressants, N06ax	22	(1.0)	25	(1.1)	47	(1.1)
Duloxetine	6	(0.3)	4	(0.2)	10	(0.2)
Duloxetine Hydrochloride	4	(0.2)	6	(0.3)	10	(0.2)
Bupropion Hydrochloride	1	(0.1)	6	(0.3)	7	(0.2)
Trazodone	1	(0.1)	6	(0.3)	7	(0.2)
Venlafaxine Hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Vortioxetine Hydrobromide	1	(0.1)	3	(0.1)	4	(0.1)
Bupropion	3	(0.1)	0		3	(0.1)
Mirtazapine	1	(0.1)	1	(0.1)	2	(0.1)
Tianeptine Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Venlafaxine	1	(0.1)	1	(0.1)	2	(0.1)
Desvenlafaxine	1	(0.1)	0		1	(0.0)
Trazodone Hydrochloride	1	(0.1)	0		1	(0.0)
Oxicams, M01ac	26	(1.2)	21	(1.0)	47	(1.1)
Meloxicam	21	(1.0)	13	(0.6)	34	(0.8)
Lornoxicam	3	(0.1)	5	(0.2)	8	(0.2)
Piroxicam	1	(0.1)	2	(0.1)	3	(0.1)
Tenoxicam	1	(0.1)	1	(0.1)	2	(0.1)
Benzodiazepine Derivatives, N05ba	17	(0.8)	29	(1.3)	46	(1.1)
Diazepam	2	(0.1)	17	(0.8)	19	(0.4)
Alprazolam	6	(0.3)	4	(0.2)	10	(0.2)
Lorazepam	6	(0.3)	3	(0.1)	9	(0.2)
Bromazepam	1	(0.1)	1	(0.1)	2	(0.1)
Ethyl Loflazepate	0		2	(0.1)	2	(0.1)
Clotiazepam	0		1	(0.1)	1	(0.0)
Etizolam	1	(0.1)	0		1	(0.0)
Medazepam	1	(0.1)	0		1	(0.0)
Phenazepam	0		1	(0.1)	1	(0.0)
Selective Beta-2-Adrenoreceptor Agonists, R03ac	29	(1.3)	16	(0.7)	45	(1.0)
Salbutamol	18	(0.8)	8	(0.4)	26	(0.6)
Salbutamol Sulfate	6	(0.3)	4	(0.2)	10	(0.2)
Tulobuterol	2	(0.1)	3	(0.1)	5	(0.1)
Ipratropium Bromide; Salbutamol Sulfate	3	(0.1)	0		3	(0.1)
Ipratropium; Salbutamol	1	(0.1)	1	(0.1)	2	(0.1)
Vilanterol Trifenatate	1	(0.1)	1	(0.1)	2	(0.1)
Indacaterol	1	(0.1)	0		1	(0.0)
Indacaterol Maleate	1	(0.1)	0		1	(0.0)
Ipratropium Bromide; Salbutamol	0		1	(0.1)	1	(0.0)
Vilanterol	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Selective Serotonin Reuptake Inhibitors, N06ab	24	(1.1)	20	(0.9)	44	(1.0)
Escitalopram	7	(0.3)	2	(0.1)	9	(0.2)
Sertraline	3	(0.1)	6	(0.3)	9	(0.2)
Escitalopram Oxalate	4	(0.2)	1	(0.1)	5	(0.1)
Sertraline Hydrochloride	3	(0.1)	2	(0.1)	5	(0.1)
Citalopram	3	(0.1)	1	(0.1)	4	(0.1)
Citalopram Hydrobromide	2	(0.1)	1	(0.1)	3	(0.1)
Fluoxetine	1	(0.1)	1	(0.1)	2	(0.1)
Fluoxetine Hydrochloride	0		2	(0.1)	2	(0.1)
Paroxetine	0		2	(0.1)	2	(0.1)
Paroxetine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Fluvoxamine Maleate	0		1	(0.1)	1	(0.0)
Aminoalkyl Ethers, R06aa	21	(1.0)	21	(1.0)	42	(1.0)
Diphenhydramine Hydrochloride	14	(0.7)	7	(0.3)	21	(0.5)
Diphenhydramine	6	(0.3)	9	(0.4)	15	(0.3)
Piprinhydrinate	1	(0.1)	1	(0.1)	2	(0.1)
Diphenhydramine Hydrochloride; Naphazoline Hydrochloride	0		1	(0.1)	1	(0.0)
Diphenhydramine Hydrochloride; Paracetamol	0		1	(0.1)	1	(0.0)
Diphenhydramine Salicylate	0		1	(0.1)	1	(0.0)
Diphenylpyraline Hydrochloride	0		1	(0.1)	1	(0.0)
Doxylamine Succinate	0		1	(0.1)	1	(0.0)
Thiazides, Plain, C03aa	28	(1.3)	14	(0.7)	42	(1.0)
Hydrochlorothiazide	27	(1.2)	14	(0.7)	41	(0.9)
Trichlormethiazide	1	(0.1)	0		1	(0.0)
Expectorants, R05ca	19	(0.9)	22	(1.0)	41	(0.9)
Guaifenesin	17	(0.8)	18	(0.8)	35	(0.8)
Guaifenesin; Pseudoephedrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Bromhexine Hydrochloride; Guaifenesin; Menthol; Terbutaline Sulfate	0		1	(0.1)	1	(0.0)
Bromhexine Hydrochloride; Guaifenesin; Salbutamol Sulfate	0		1	(0.1)	1	(0.0)
Drosera Rotundifolia Extract; Ephedrine Hydrochloride; Saponin; Thymus Vulgaris Oil	1	(0.1)	0		1	(0.0)
Expectorants	1	(0.1)	0		1	(0.0)
Myrtol	0		1	(0.1)	1	(0.0)
Tetracyclines, J01aa	23	(1.1)	18	(0.8)	41	(0.9)
Doxycycline	20	(0.9)	14	(0.7)	34	(0.8)
Doxycycline Hyclate	2	(0.1)	3	(0.1)	5	(0.1)
Minocycline Hydrochloride	2	(0.1)	0		2	(0.1)
Doxycycline Hydrochloride	1	(0.1)	0		1	(0.0)
Doxycycline Monohydrate	0		1	(0.1)	1	(0.0)
Other Cough Suppressants, R05db	22	(1.0)	16	(0.7)	38	(0.9)
Benzonatate	13	(0.6)	9	(0.4)	22	(0.5)
Cloperastine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Levodropropizine	2	(0.1)	0		2	(0.1)
Other Cough Suppressants	2	(0.1)	0		2	(0.1)
Oxolamine Phosphate	0		2	(0.1)	2	(0.1)
Benproperine	0		1	(0.1)	1	(0.0)
Butamirate Citrate	0		1	(0.1)	1	(0.0)
Clobutinol Hydrochloride	1	(0.1)	0		1	(0.0)
Clofedanol Hydrochloride	1	(0.1)	0		1	(0.0)
Dropropizine	0		1	(0.1)	1	(0.0)
Oxolamine Citrate	0		1	(0.1)	1	(0.0)
Pentoxyverine	1	(0.1)	0		1	(0.0)
Tipepidine Hibenzate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Potassium, A12ba	20	(0.9)	18	(0.8)	38	(0.9)
Potassium Chloride	14	(0.7)	15	(0.7)	29	(0.7)
Calcium Chloride Dihydrate; Glucose; Potassium Chloride; Sodium Lactate	1	(0.1)	1	(0.1)	2	(0.1)
Potassium Chloride; Sodium Chloride	2	(0.1)	0		2	(0.1)
Calcium Chloride Dihydrate; Glucose; Potassium Chloride; Sodium Acetate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Calcium Chloride Dihydrate; Magnesium Chloride Hexahydrate; Potassium Chloride; Sodium Acetate Trihydrate; Sodium Chloride; Sodium Citrate Dihydrate	1	(0.1)	0		1	(0.0)
Calcium Chloride; Potassium Chloride; Sodium Acetate; Sodium Chloride	1	(0.1)	0		1	(0.0)
Glucose; Potassium Chloride; Sodium Chloride; Sodium Citrate	1	(0.1)	0		1	(0.0)
Macrogol 4000; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate	1	(0.1)	0		1	(0.0)
Macrogol 4000; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate Anhydrous	1	(0.1)	0		1	(0.0)
Magnesium Sulfate; Potassium Chloride	0		1	(0.1)	1	(0.0)
Contact Laxatives, A06ab	18	(0.8)	18	(0.8)	36	(0.8)
Bisacodyl	3	(0.1)	6	(0.3)	9	(0.2)
Sennoside A+B	4	(0.2)	4	(0.2)	8	(0.2)
Citric Acid; Magnesium Oxide; Sodium Picosulfate	4	(0.2)	2	(0.1)	6	(0.1)
Sennoside A+B Calcium	2	(0.1)	3	(0.1)	5	(0.1)
Sodium Picosulfate	2	(0.1)	2	(0.1)	4	(0.1)
Docusate; Senna Alexandrina	1	(0.1)	2	(0.1)	3	(0.1)
Contact Laxatives	1	(0.1)	1	(0.1)	2	(0.1)
Docusate Sodium; Sennoside A+B	2	(0.1)	0		2	(0.1)
Bisacodyl; Docusate Sodium; Sennoside A+B	0		1	(0.1)	1	(0.0)
Docusate Sodium; Senna Alexandrina	1	(0.1)	0		1	(0.0)
Phenolphthalein	1	(0.1)	0		1	(0.0)
Sodium Picosulfate Monohydrate	0		1	(0.1)	1	(0.0)
Serotonin (5ht3) Antagonists, A04aa	19	(0.9)	17	(0.8)	36	(0.8)
Ondansetron	16	(0.7)	15	(0.7)	31	(0.7)
Ondansetron Hydrochloride	3	(0.1)	2	(0.1)	5	(0.1)
Granisetron	1	(0.1)	0		1	(0.0)
Palonosetron	1	(0.1)	0		1	(0.0)
Alpha And Beta Blocking Agents, C07ag	16	(0.7)	18	(0.8)	34	(0.8)
Carvedilol	14	(0.7)	16	(0.7)	30	(0.7)
Labetalol	2	(0.1)	3	(0.1)	5	(0.1)
Iron Bivalent, Oral Preparations, B03aa	16	(0.7)	18	(0.8)	34	(0.8)
Ferrous Glycine Sulfate	6	(0.3)	7	(0.3)	13	(0.3)
Ferrous Sulfate	5	(0.2)	8	(0.4)	13	(0.3)
Ferrous Fumarate	4	(0.2)	2	(0.1)	6	(0.1)
Ferrous Sodium Citrate	0		3	(0.1)	3	(0.1)
Ferrous Ascorbate	1	(0.1)	0		1	(0.0)
Benzodiazepine Derivatives, N05cd	17	(0.8)	16	(0.7)	33	(0.8)
Midazolam	4	(0.2)	10	(0.5)	14	(0.3)
Midazolam Hydrochloride	4	(0.2)	1	(0.1)	5	(0.1)
Temazepam	3	(0.1)	1	(0.1)	4	(0.1)
Brotizolam	2	(0.1)	1	(0.1)	3	(0.1)
Nitrazepam	1	(0.1)	2	(0.1)	3	(0.1)
Estazolam	1	(0.1)	1	(0.1)	2	(0.1)
Flurazepam Hydrochloride	1	(0.1)	0		1	(0.0)
Loprazolam Mesilate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Pneumococcal Vaccines, J07al	18	(0.8)	15	(0.7)	33	(0.8)
Pneumococcal Vaccine	7	(0.3)	6	(0.3)	13	(0.3)
Pneumococcal Vaccine Polysacch 23v	8	(0.4)	5	(0.2)	13	(0.3)
Pneumococcal Vaccine Conj 7v (Crm197)	1	(0.1)	2	(0.1)	3	(0.1)
Pneumococcal Vaccine Conj 13v (Crm197)	1	(0.1)	1	(0.1)	2	(0.1)
Pneumococcal Vaccine 13v	1	(0.1)	0		1	(0.0)
Pneumococcal Vaccine Polyv	0		1	(0.1)	1	(0.0)
Aldosterone Antagonists, C03da	18	(0.8)	13	(0.6)	31	(0.7)
Spironolactone	15	(0.7)	9	(0.4)	24	(0.6)
Eplerenone	3	(0.1)	1	(0.1)	4	(0.1)
Esaxerenone	0		2	(0.1)	2	(0.1)
Potassium Canrenoate	0		1	(0.1)	1	(0.0)
Antidiarrheal Microorganisms, A07fa	18	(0.8)	13	(0.6)	31	(0.7)
Saccharomyces Boulardii	6	(0.3)	1	(0.1)	7	(0.2)
Bifidobacterium Nos	4	(0.2)	2	(0.1)	6	(0.1)
Bacillus Mesentericus; Clostridium Butyricum; Enterococcus Faecalis	3	(0.1)	1	(0.1)	4	(0.1)
Antibiotics-Resistant Lactic Acid Bacteriae	1	(0.1)	1	(0.1)	2	(0.1)
Bifidobacterium Lactis	1	(0.1)	1	(0.1)	2	(0.1)
Enterococcus Faecalis	1	(0.1)	1	(0.1)	2	(0.1)
Lactobacillus Helveticus; Lactobacillus Rhamnosus	1	(0.1)	1	(0.1)	2	(0.1)
Bacillus Lichenformis	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum	1	(0.1)	0		1	(0.0)
Bifidobacterium Bifidum; Bifidobacterium Infantis	1	(0.1)	0		1	(0.0)
Bifidobacterium Breve; Bifidobacterium Infantis; Bifidobacterium Longum; Lactobacillus Acidophilus; Lactobacillus Bulgaricus; Lactobacillus Paracasei; Lactobacillus Plantarum; Streptococcus Thermophilus	0		1	(0.1)	1	(0.0)
Bifidobacterium Lactis; Fructooligosaccharides; Inulin; Lactobacillus Acidophilus; Lactobacillus Casei; Lactobacillus Plantarum; Lactobacillus Salivarius	0		1	(0.1)	1	(0.0)
Bifidobacterium Longum; Enterococcus Faecalis; Lactobacillus Acidophilus	1	(0.1)	0		1	(0.0)
Bifidobacterium Longum; Enterococcus Faecium	0		1	(0.1)	1	(0.0)
Enterococcus Faecalis; Escherichia Coli; Lactobacillus Acidophilus; Lactobacillus Helveticus	0		1	(0.1)	1	(0.0)
Second-Generation Cephalosporins, J01dc	21	(1.0)	10	(0.5)	31	(0.7)
Cefuroxime Axetil	9	(0.4)	4	(0.2)	13	(0.3)
Cefaclor	8	(0.4)	3	(0.1)	11	(0.2)
Cefprozil	2	(0.1)	1	(0.1)	3	(0.1)
Cefaclor Monohydrate	1	(0.1)	0		1	(0.0)
Cefmetazole Sodium	0		1	(0.1)	1	(0.0)
Cefoxitin	0		1	(0.1)	1	(0.0)
Cefprozil Monohydrate	1	(0.1)	0		1	(0.0)
Alpha-Adrenoreceptor Antagonists, G04ca	16	(0.7)	14	(0.7)	30	(0.7)
Tamsulosin	8	(0.4)	4	(0.2)	12	(0.3)
Tamsulosin Hydrochloride	6	(0.3)	4	(0.2)	10	(0.2)
Silodosin	3	(0.1)	2	(0.1)	5	(0.1)
Terazosin	0		2	(0.1)	2	(0.1)
Alfuzosin Hydrochloride	0		1	(0.1)	1	(0.0)
Terazosin Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Leukotriene Receptor Antagonists, R03dc	13	(0.6)	17	(0.8)	30	(0.7)
Montelukast	6	(0.3)	6	(0.3)	12	(0.3)
Montelukast Sodium	4	(0.2)	8	(0.4)	12	(0.3)
Levocetirizine Dihydrochloride; Montelukast Sodium	3	(0.1)	2	(0.1)	5	(0.1)
Levocetirizine; Montelukast	1	(0.1)	1	(0.1)	2	(0.1)
Sympathomimetics, R01ba	15	(0.7)	14	(0.7)	29	(0.7)
Pseudoephedrine Hydrochloride	6	(0.3)	9	(0.4)	15	(0.3)
Pseudoephedrine	5	(0.2)	3	(0.1)	8	(0.2)
Pseudoephedrine Hydrochloride; Triprolidine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Atropa Belladonna Extract; Caffeine; Carbinoxamine Maleate; Lysozyme Chloride; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Atropa Belladonna Total Alkaloid Extract; Caffeine; Dipotassium Glycyrrhizate; Mequitazine; Methylephedrine Hydrochloride-Dl; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Diphenhydramine Hydrochloride; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Loratadine; Pseudoephedrine Sulfate	1	(0.1)	0		1	(0.0)
H2-Receptor Antagonists, A02ba	21	(1.0)	7	(0.3)	28	(0.7)
Famotidine	16	(0.7)	7	(0.3)	23	(0.5)
Cimetidine	1	(0.1)	0		1	(0.0)
Domperidone; Ranitidine	1	(0.1)	0		1	(0.0)
Lafutidine	1	(0.1)	0		1	(0.0)
Ondansetron Hydrochloride; Ranitidine Hydrochloride	1	(0.1)	0		1	(0.0)
Ranitidine	1	(0.1)	0		1	(0.0)
Corticosteroids, R01ad	16	(0.7)	11	(0.5)	27	(0.6)
Fluticasone Propionate	16	(0.7)	9	(0.4)	25	(0.6)
Azelastine Hydrochloride; Fluticasone Propionate	0		1	(0.1)	1	(0.0)
Dexamethasone Cipecilate	0		1	(0.1)	1	(0.0)
Sulfonamides, Plain, C03ba	15	(0.7)	12	(0.6)	27	(0.6)
Indapamide	11	(0.5)	10	(0.5)	21	(0.5)
Chlortalidone	4	(0.2)	2	(0.1)	6	(0.1)
Thyroid Hormones, H03aa	18	(0.8)	9	(0.4)	27	(0.6)
Levothyroxine Sodium	11	(0.5)	6	(0.3)	17	(0.4)
Levothyroxine	7	(0.3)	3	(0.1)	10	(0.2)
Liothyronine	1	(0.1)	0		1	(0.0)
Antipropulsives, A07da	17	(0.8)	8	(0.4)	25	(0.6)
Loperamide Hydrochloride	9	(0.4)	5	(0.2)	14	(0.3)
Loperamide	7	(0.3)	3	(0.1)	10	(0.2)
Diphenoxylate	1	(0.1)	0		1	(0.0)
Magnesium Compounds, A02aa	7	(0.3)	18	(0.8)	25	(0.6)
Magnesium Oxide	6	(0.3)	15	(0.7)	21	(0.5)
Magnesium Hydroxide	1	(0.1)	3	(0.1)	4	(0.1)
Nitrofuran Derivatives, J01xe	11	(0.5)	14	(0.7)	25	(0.6)
Nitrofurantoin	9	(0.4)	12	(0.6)	21	(0.5)
Furazidin	1	(0.1)	2	(0.1)	3	(0.1)
Nitrofurantoin Monohydrate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors, J05ab	14	(0.7)	11	(0.5)	25	(0.6)
Valaciclovir Hydrochloride	7	(0.3)	7	(0.3)	14	(0.3)
Valaciclovir	4	(0.2)	3	(0.1)	7	(0.2)
Remdesivir	3	(0.1)	2	(0.1)	5	(0.1)
Drugs For Urinary Frequency And Incontinence, G04bd	13	(0.6)	11	(0.5)	24	(0.6)
Mirabegron	6	(0.3)	3	(0.1)	9	(0.2)
Oxybutynin	1	(0.1)	2	(0.1)	3	(0.1)
Propiverine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Tolterodine L-Tartrate	2	(0.1)	1	(0.1)	3	(0.1)
Vibegron	1	(0.1)	2	(0.1)	3	(0.1)
Oxybutynin Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Fesoterodine	1	(0.1)	0		1	(0.0)
Fesoterodine Fumarate	0		1	(0.1)	1	(0.0)
Flavoxate Hydrochloride	1	(0.1)	0		1	(0.0)
Solifenacin Succinate	0		1	(0.1)	1	(0.0)
Tolterodine	0		1	(0.1)	1	(0.0)
Preparations Inhibiting Uric Acid Production, M04aa	14	(0.7)	10	(0.5)	24	(0.6)
Allopurinol	11	(0.5)	8	(0.4)	19	(0.4)
Febuxostat	3	(0.1)	2	(0.1)	5	(0.1)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds, A03bb	11	(0.5)	12	(0.6)	23	(0.5)
Hyoscine Butylbromide	11	(0.5)	11	(0.5)	22	(0.5)
Cimetropium Bromide	0		1	(0.1)	1	(0.0)
Calcium, A12aa	11	(0.5)	12	(0.6)	23	(0.5)
Calcium Carbonate	4	(0.2)	6	(0.3)	10	(0.2)
Calcium	3	(0.1)	5	(0.2)	8	(0.2)
Calcium Citrate	3	(0.1)	2	(0.1)	5	(0.1)
Calcium Carbonate; Calcium Lactate Gluconate	1	(0.1)	0		1	(0.0)
Non-Selective Monoamine Reuptake Inhibitors, N06aa	11	(0.5)	12	(0.6)	23	(0.5)
Amitriptyline	7	(0.3)	5	(0.2)	12	(0.3)
Amitriptyline Hydrochloride	2	(0.1)	4	(0.2)	6	(0.1)
Nortriptyline	2	(0.1)	1	(0.1)	3	(0.1)
Nortriptyline Hydrochloride	0		1	(0.1)	1	(0.0)
Opipramol Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Opium Derivatives And Expectorants, R05fa	10	(0.5)	13	(0.6)	23	(0.5)
Dextromethorphan Hydrobromide; Guaifenesin	4	(0.2)	7	(0.3)	11	(0.2)
Ammonia; Benzoic Acid; Camphor; Glycerol; Glycyrrhiza Spp. Root With Rhizome; Guaifenesin; Illicium Verum Oil; Papaver Somniferum Tincture	1	(0.1)	2	(0.1)	3	(0.1)
Dextromethorphan; Guaifenesin	1	(0.1)	1	(0.1)	2	(0.1)
Ammonium Chloride; Aster Tataricus Root With Rhizome; Citrus Aurantium Epicarp; Citrus Aurantium Fruit Peel; Citrus Aurantium Unripe Fruit; Glycyrrhiza Spp. Root With Rhizome; Mentha Canadensis Herb Oil; Pap	0		1	(0.1)	1	(0.0)
Ammonium Chloride; Bromhexine; Dextromethorphan; Menthol	1	(0.1)	0		1	(0.0)
Ammonium Chloride; Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Guaifenesin	0		1	(0.1)	1	(0.0)
Antimony Potassium Tartrate; Papaver Somniferum Tincture; Terpin	1	(0.1)	0		1	(0.0)
Codeine Phosphate; Guaifenesin	0		1	(0.1)	1	(0.0)
Codeine; Guaifenesin	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin; Phenylephrine	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Dextromethorphan; Guaifenesin; Phenylephrine	1	(0.1)	0		1	(0.0)
Propulsives, A03fa	7	(0.3)	16	(0.7)	23	(0.5)
Domperidone	4	(0.2)	8	(0.4)	12	(0.3)
Mosapride Citrate	2	(0.1)	5	(0.2)	7	(0.2)
Cinitapride	0		3	(0.1)	3	(0.1)
Domperidone Maleate	1	(0.1)	0		1	(0.0)
Tranexamic Acid, B02aa02	12	(0.6)	11	(0.5)	23	(0.5)
Tranexamic Acid	12	(0.6)	10	(0.5)	22	(0.5)
Glycyrrhiza Spp.; Pyridoxine Hydrochloride; Riboflavin; Sodium Ascorbate; Tranexamic Acid	0		1	(0.1)	1	(0.0)
Amides, N01bb	13	(0.6)	9	(0.4)	22	(0.5)
Ropivacaine	4	(0.2)	1	(0.1)	5	(0.1)
Mepivacaine Hydrochloride	4	(0.2)	0		4	(0.1)
Epinephrine; Lidocaine	0		3	(0.1)	3	(0.1)
Trimecaine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Mepivacaine	2	(0.1)	0		2	(0.1)
Articaine Hydrochloride	0		1	(0.1)	1	(0.0)
Articaine Hydrochloride; Epinephrine Bitartrate	0		1	(0.1)	1	(0.0)
Articaine Hydrochloride; Epinephrine Hydrochloride	0		1	(0.1)	1	(0.0)
Articaine; Epinephrine	1	(0.1)	0		1	(0.0)
Epinephrine Bitartrate; Lidocaine Hydrochloride	1	(0.1)	0		1	(0.0)
Epinephrine Hydrochloride; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Ropivacaine Hydrochloride	1	(0.1)	0		1	(0.0)
Carbohydrates, V06dc	11	(0.5)	11	(0.5)	22	(0.5)
Glucose	9	(0.4)	10	(0.5)	19	(0.4)
Glucose; Sodium Chloride	3	(0.1)	0		3	(0.1)
Electrolytes Nos; Glucose	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Osmotically Acting Laxatives, A06ad	9	(0.4)	13	(0.6)	22	(0.5)
Lactulose	4	(0.2)	3	(0.1)	7	(0.2)
Macrogol 3350	4	(0.2)	3	(0.1)	7	(0.2)
Ascorbic Acid; Macrogol 3350; Potassium Chloride; Sodium Ascorbate; Sodium Chloride; Sodium Sulfate	2	(0.1)	3	(0.1)	5	(0.1)
Ascorbic Acid; Macrogol 3350; Potassium Chloride; Sodium Ascorbate; Sodium Chloride; Sodium Sulfate Anhydrous	0		1	(0.1)	1	(0.0)
Macrogol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Macrogol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate	0		1	(0.1)	1	(0.0)
Macrogol; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate Anhydrous	0		1	(0.1)	1	(0.0)
Phenylpiperidine Derivatives, N02ab	9	(0.4)	13	(0.6)	22	(0.5)
Fentanyl	6	(0.3)	6	(0.3)	12	(0.3)
Pethidine Hydrochloride	2	(0.1)	3	(0.1)	5	(0.1)
Fentanyl Citrate	1	(0.1)	2	(0.1)	3	(0.1)
Pethidine	0		2	(0.1)	2	(0.1)
Thiazolidinediones, A10bg	10	(0.5)	12	(0.6)	22	(0.5)
Pioglitazone	6	(0.3)	9	(0.4)	15	(0.3)
Pioglitazone Hydrochloride	4	(0.2)	2	(0.1)	6	(0.1)
Lobeglitazone	0		1	(0.1)	1	(0.0)
Vitamin B1, Plain, A11da	13	(0.6)	9	(0.4)	22	(0.5)
Thiamine Hydrochloride	5	(0.2)	5	(0.2)	10	(0.2)
Thiamine	4	(0.2)	3	(0.1)	7	(0.2)
Benfotiamine	3	(0.1)	2	(0.1)	5	(0.1)
Fursultiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Antivertigo Preparations, N07ca	8	(0.4)	13	(0.6)	21	(0.5)
Betahistine Hydrochloride	3	(0.1)	6	(0.3)	9	(0.2)
Betahistine	4	(0.2)	4	(0.2)	8	(0.2)
Betahistine Mesilate	2	(0.1)	2	(0.1)	4	(0.1)
Cinnarizine	1	(0.1)	1	(0.1)	2	(0.1)
Organic Nitrates, C01da	9	(0.4)	12	(0.6)	21	(0.5)
Glyceryl Trinitrate	6	(0.3)	11	(0.5)	17	(0.4)
Isosorbide Mononitrate	3	(0.1)	1	(0.1)	4	(0.1)
Isosorbide Dinitrate	0		2	(0.1)	2	(0.1)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics, R03ak	10	(0.5)	10	(0.5)	20	(0.5)
Budesonide; Formoterol Fumarate	4	(0.2)	3	(0.1)	7	(0.2)
Beclometasone Dipropionate; Formoterol Fumarate	2	(0.1)	2	(0.1)	4	(0.1)
Fluticasone Furoate; Vilanterol Trifenatate	1	(0.1)	2	(0.1)	3	(0.1)
Fluticasone Propionate; Salmeterol Xinafoate	1	(0.1)	2	(0.1)	3	(0.1)
Fluticasone; Salmeterol	1	(0.1)	1	(0.1)	2	(0.1)
Formoterol Fumarate; Mometasone Furoate	2	(0.1)	0		2	(0.1)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives, J01ee	9	(0.4)	11	(0.5)	20	(0.5)
Sulfamethoxazole; Trimethoprim	9	(0.4)	11	(0.5)	20	(0.5)

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adsl.xpt; variable(s): NA; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y")
adcm.xpt; variable(s): TRAG1 CMDECOD CMCLAS CMCLASCD; criteria: (POOLGR2 == "Phase 3a pool" & SAFFL == "Y") & (SCSTT == "AFTER")

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Antibacterials, J01xx	10	(0.5)	10	(0.5)	20	(0.5)
Fosfomycin	6	(0.3)	3	(0.1)	9	(0.2)
Fosfomycin Trometamol	1	(0.1)	3	(0.1)	4	(0.1)
Linezolid	1	(0.1)	3	(0.1)	4	(0.1)
D-Mannose	1	(0.1)	0		1	(0.0)
Fosfomycin Calcium	0		1	(0.1)	1	(0.0)
Methenamine	1	(0.1)	0		1	(0.0)
Methenamine Anhydromethylenecitrate	1	(0.1)	0		1	(0.0)
Magnesium, A12cc	9	(0.4)	10	(0.5)	19	(0.4)
Magnesium	5	(0.2)	9	(0.4)	14	(0.3)
Magnesium Aspartate	1	(0.1)	0		1	(0.0)
Magnesium Aspartate Hydrochloride	1	(0.1)	0		1	(0.0)
Magnesium Gluconate	0		1	(0.1)	1	(0.0)
Magnesium Glycinate	1	(0.1)	0		1	(0.0)
Magnesium Pidolate	1	(0.1)	0		1	(0.0)
Other Ophthalmologicals, S01xa	11	(0.5)	8	(0.4)	19	(0.4)
Pirenoxine	3	(0.1)	0		3	(0.1)
Hyaluronate Sodium; Trehalose	1	(0.1)	1	(0.1)	2	(0.1)
Paraffin; Paraffin, Liquid; Retinol Palmitate; White Soft Paraffin; Wool Fat	2	(0.1)	0		2	(0.1)
Artificial Tears [Umbrella Term]	1	(0.1)	0		1	(0.0)
Azapentacene Polysulfonate Sodium	1	(0.1)	0		1	(0.0)
Calcium Chloride Dihydrate; Glucose; Glutathione; Magnesium Chloride; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Phosphate	0		1	(0.1)	1	(0.0)
Carmellose Sodium; Glycerol	0		1	(0.1)	1	(0.0)
Carmellose; Glycerol	0		1	(0.1)	1	(0.0)
Citicoline Sodium; Cyanocobalamin; Hyaluronic Acid; Sodium Chloride; Sodium Phosphate Dibasic Dodecahydrate; Sodium Phosphate Monobasic (Monohydrate)	0		1	(0.1)	1	(0.0)
Diquafosol Tetrasodium	0		1	(0.1)	1	(0.0)
Docosahexaenoic Acid; Eicosapentaenoic Acid; Xantofyl; Zeaxanthin	1	(0.1)	0		1	(0.0)
Hyaluronate Sodium; Macrogol 400; Propylene Glycol	0		1	(0.1)	1	(0.0)
Iodolecithin	1	(0.1)	0		1	(0.0)
Macrogol 400; Propylene Glycol	0		1	(0.1)	1	(0.0)
Trehalose	1	(0.1)	0		1	(0.0)
Varicella Zoster Vaccines, J07bk	10	(0.5)	9	(0.4)	19	(0.4)
Varicella Zoster Vaccine Rge (Cho)	8	(0.4)	8	(0.4)	16	(0.4)
Varicella Zoster Vaccine Live (Oka/Merck)	2	(0.1)	0		2	(0.1)
Varicella Zoster Vaccine Live (Oka)	0		1	(0.1)	1	(0.0)
Various Alimentary Tract And Metabolism Products, A16ax	8	(0.4)	11	(0.5)	19	(0.4)
Thioctic Acid	8	(0.4)	10	(0.5)	18	(0.4)
Thioctic Acid Sodium	0		2	(0.1)	2	(0.1)
Diphenylmethane Derivatives, N05bb	6	(0.3)	12	(0.6)	18	(0.4)
Hydroxyzine Hydrochloride	3	(0.1)	7	(0.3)	10	(0.2)
Hydroxyzine	3	(0.1)	4	(0.2)	7	(0.2)
Hydroxyzine Embonate	0		1	(0.1)	1	(0.0)
Alpha-Adrenoreceptor Antagonists, C02ca	10	(0.5)	7	(0.3)	17	(0.4)
Doxazosin	6	(0.3)	2	(0.1)	8	(0.2)
Doxazosin Mesilate	2	(0.1)	4	(0.2)	6	(0.1)
Urapidil	2	(0.1)	1	(0.1)	3	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Blood Glucose Lowering Drugs, Excl. Insulins, A10bx	7	(0.3)	9	(0.4)	16	(0.4)
Repaglinide	5	(0.2)	6	(0.3)	11	(0.2)
Mitiglinide Calcium	1	(0.1)	1	(0.1)	2	(0.1)
Nateglinide	0		2	(0.1)	2	(0.1)
Bromocriptine Mesilate	1	(0.1)	0		1	(0.0)
Solutions Affecting The Electrolyte Balance, B05bb	8	(0.4)	8	(0.4)	16	(0.4)
Calcium Chloride Dihydrate; Potassium Chloride; Sodium Chloride; Sodium Lactate	3	(0.1)	1	(0.1)	4	(0.1)
Gluconate Sodium; Magnesium Chloride Hexahydrate; Potassium Chloride; Sodium Acetate Trihydrate; Sodium Chloride	2	(0.1)	2	(0.1)	4	(0.1)
Calcium Chloride; Potassium Chloride; Sodium Lactate	0		3	(0.1)	3	(0.1)
Glucose; Sodium Chloride; Sodium Lactate	2	(0.1)	0		2	(0.1)
Potassium Chloride; Sodium Chloride; Sodium Lactate	1	(0.1)	1	(0.1)	2	(0.1)
Calcium Chloride; Glucose Monohydrate; Potassium Chloride; Sodium Chloride; Sodium Lactate	1	(0.1)	0		1	(0.0)
Calcium Chloride; Potassium Chloride; Sodium Chloride; Sodium Lactate	0		1	(0.1)	1	(0.0)
Glucose; Magnesium Chloride Hexahydrate; Potassium Chloride; Potassium Phosphate Monobasic; Sodium Acetate Trihydrate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Glucose; Potassium Chloride	1	(0.1)	0		1	(0.0)
Alpha Glucosidase Inhibitors, A10bf	7	(0.3)	8	(0.4)	15	(0.3)
Acarbose	5	(0.2)	6	(0.3)	11	(0.2)
Voglibose	1	(0.1)	2	(0.1)	3	(0.1)
Miglitol	2	(0.1)	0		2	(0.1)
Carbamic Acid Esters, M03ba	8	(0.4)	7	(0.3)	15	(0.3)
Methocarbamol	6	(0.3)	7	(0.3)	13	(0.3)
Carisoprodol	2	(0.1)	0		2	(0.1)
Acetylsalicylic Acid; Codeine Phosphate; Methocarbamol	0		1	(0.1)	1	(0.0)
Acetylsalicylic Acid; Methocarbamol	0		1	(0.1)	1	(0.0)
Vitamins, Other Combinations, A11jc	5	(0.2)	10	(0.5)	15	(0.3)
Vitamins, Other Combinations	2	(0.1)	3	(0.1)	5	(0.1)
Colecalciferol; Folic Acid; Mecobalamin; Pyridoxine Hydrochloride; Thioctic Acid	1	(0.1)	3	(0.1)	4	(0.1)
Ascorbic Acid; Herbal Nos; Levoglutamide; Lysine; Magnesium; Manganese; Retinol; Riboflavin; Selenium; Tocopherol; Zinc	0		2	(0.1)	2	(0.1)
Cyanocobalamin; Lidocaine Hydrochloride; Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate Dibasic; Colecalciferol; Copper Sulfate; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Magnesium Oxide; Manganese Sulfate; Nicotinamide; Po	0		1	(0.1)	1	(0.0)
Cyanocobalamin; Folic Acid; Thiamine Mononitrate; Thioctic Acid	1	(0.1)	0		1	(0.0)
Eucalyptus Globulus Oil; Pyridoxine Hydrochloride; Vitamin B1 Nos	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media, V08ab	11	(0.5)	4	(0.2)	15	(0.3)
Iohexol	5	(0.2)	2	(0.1)	7	(0.2)
Iopamidol	5	(0.2)	1	(0.1)	6	(0.1)
Iodixanol	1	(0.1)	0		1	(0.0)
Iopromide	0		1	(0.1)	1	(0.0)
Ioversol	0		1	(0.1)	1	(0.0)
Antiarrhythmics, Class Iii, C01bd	6	(0.3)	8	(0.4)	14	(0.3)
Amiodarone	3	(0.1)	6	(0.3)	9	(0.2)
Amiodarone Hydrochloride	3	(0.1)	2	(0.1)	5	(0.1)
Benzodiazepine Related Drugs, N05cf	6	(0.3)	8	(0.4)	14	(0.3)
Zolpidem	3	(0.1)	3	(0.1)	6	(0.1)
Zolpidem Tartrate	2	(0.1)	3	(0.1)	5	(0.1)
Zopiclone	1	(0.1)	1	(0.1)	2	(0.1)
Eszopiclone	0		1	(0.1)	1	(0.0)
Corticosteroids And Antiinfectives In Combination, S01ca	8	(0.4)	6	(0.3)	14	(0.3)
Dexamethasone; Tobramycin	6	(0.3)	2	(0.1)	8	(0.2)
Dexamethasone; Neomycin Sulfate; Polymyxin B Sulfate	2	(0.1)	2	(0.1)	4	(0.1)
Betamethasone Sodium Phosphate; Chloramphenicol; Colistimethate Sodium; Rolitetracycline	1	(0.1)	1	(0.1)	2	(0.1)
Dexamethasone Sodium Phosphate; Levofloxacin Hemihydrate	0		1	(0.1)	1	(0.0)
Enzyme Preparations, A09aa	7	(0.3)	7	(0.3)	14	(0.3)
Pancreatin	6	(0.3)	3	(0.1)	9	(0.2)
Cellulase; Enzymes Nos; Pancreatic Digestive Enzyme Ta; Proctase; Sanactase	1	(0.1)	2	(0.1)	3	(0.1)
Pancreatin; Pepsin	0		1	(0.1)	1	(0.0)
Pancrelipase	0		1	(0.1)	1	(0.0)
Folic Acid And Derivatives, B03bb	9	(0.4)	5	(0.2)	14	(0.3)
Folic Acid	8	(0.4)	4	(0.2)	12	(0.3)
Ascorbic Acid; Folic Acid; Mecobalamin; Nicotinamide	1	(0.1)	0		1	(0.0)
Doxylamine Succinate; Folic Acid; Pyridoxine Hydrochloride	0		1	(0.1)	1	(0.0)
Imidazoline Receptor Agonists, C02ac	7	(0.3)	7	(0.3)	14	(0.3)
Clonidine	3	(0.1)	2	(0.1)	5	(0.1)
Moxonidine	2	(0.1)	3	(0.1)	5	(0.1)
Clonidine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Rilmenidine	0		1	(0.1)	1	(0.0)
Rilmenidine Phosphate	1	(0.1)	0		1	(0.0)
Other Drugs For Functional Gastrointestinal Disorders, A03ax	5	(0.2)	9	(0.4)	14	(0.3)
Simeticone	2	(0.1)	4	(0.2)	6	(0.1)
Pinaverium Bromide	0		2	(0.1)	2	(0.1)
Alverine Citrate; Simeticone	0		1	(0.1)	1	(0.0)
Atractylodes Macrocephala, Rhizoma; Glycyrrhiza Spp. Root With Rhizome; Levoglutamide; Panax Ginseng Root With Rhizome; Poria Cocos Sclerotium	1	(0.1)	0		1	(0.0)
Dimeticone; Guaiazulene	1	(0.1)	0		1	(0.0)
Fenoverine	1	(0.1)	0		1	(0.0)
Flopropione	0		1	(0.1)	1	(0.0)
Sodium Butyrate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Cardiac Preparations, C01eb	7	(0.3)	6	(0.3)	13	(0.3)
Ranolazine	1	(0.1)	2	(0.1)	3	(0.1)
Trimetazidine Hydrochloride	0		3	(0.1)	3	(0.1)
Ivabradine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Trimetazidine	2	(0.1)	0		2	(0.1)
Ubidecarenone	2	(0.1)	0		2	(0.1)
Adenosine Triphosphate, Disodium Salt	1	(0.1)	0		1	(0.0)
Ivabradine	0		1	(0.1)	1	(0.0)
Ivabradine Oxalate	0		1	(0.1)	1	(0.0)
Other General Anesthetics, N01ax	3	(0.1)	10	(0.5)	13	(0.3)
Propofol	3	(0.1)	9	(0.4)	12	(0.3)
Ketamine	0		1	(0.1)	1	(0.0)
Other Psychostimulants And Nootropics, N06bx	5	(0.2)	8	(0.4)	13	(0.3)
Piracetam	3	(0.1)	2	(0.1)	5	(0.1)
Vinpocetine	1	(0.1)	4	(0.2)	5	(0.1)
Inosine; Nicotinamide; Riboflavin; Succinic Acid	1	(0.1)	3	(0.1)	4	(0.1)
Antineovascularisation Agents, S01la	7	(0.3)	5	(0.2)	12	(0.3)
Bevacizumab	4	(0.2)	5	(0.2)	9	(0.2)
Aflibercept	4	(0.2)	0		4	(0.1)
Beta Blocking Agents, Non-Selective, C07aa	2	(0.1)	10	(0.5)	12	(0.3)
Propranolol	0		3	(0.1)	3	(0.1)
Timolol Maleate	0		3	(0.1)	3	(0.1)
Propranolol Hydrochloride	0		2	(0.1)	2	(0.1)
Sotalol Hydrochloride	0		2	(0.1)	2	(0.1)
Timolol	1	(0.1)	1	(0.1)	2	(0.1)
Nadolol	1	(0.1)	0		1	(0.0)
Salicylic Acid And Derivatives, N02ba	6	(0.3)	6	(0.3)	12	(0.3)
Salicylamide	0		4	(0.2)	4	(0.1)
Acetylsalicylic Acid; Hydrotalcite	1	(0.1)	1	(0.1)	2	(0.1)
Acetylsalicylic Acid; Ascorbic Acid	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Ascorbic Acid; Caffeine	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Ascorbic Acid; Chlorphenamine Maleate; Moroxydine Hydrochloride; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Chlorphenamine Maleate; Phenylephrine Bitartrate	0		1	(0.1)	1	(0.0)
Calcium Bromide; Cinchocaine Hydrochloride; Salicylate Sodium	1	(0.1)	0		1	(0.0)
Diflunisal	1	(0.1)	0		1	(0.0)
Antiinflammatory Agents, Non-Steroids, S01bc	4	(0.2)	7	(0.3)	11	(0.2)
Nepafenac	4	(0.2)	7	(0.3)	11	(0.2)
Bisphosphonates, M05ba	6	(0.3)	5	(0.2)	11	(0.2)
Alendronate Sodium	4	(0.2)	3	(0.1)	7	(0.2)
Bisphosphonates	1	(0.1)	0		1	(0.0)
Ibandronate Sodium	0		1	(0.1)	1	(0.0)
Risedronate Sodium	1	(0.1)	0		1	(0.0)
Zoledronic Acid	0		1	(0.1)	1	(0.0)
Corticosteroids, Potent (Group Iii), D07ac	8	(0.4)	3	(0.1)	11	(0.2)
Methylprednisolone Aceponate	4	(0.2)	1	(0.1)	5	(0.1)
Diflucortolone Valerate	2	(0.1)	1	(0.1)	3	(0.1)
Desoximetasone	2	(0.1)	0		2	(0.1)
Diflorasone Diacetate	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Synthetic Anticholinergics, Esters With Tertiary Amino Group, A03aa	4	(0.2)	7	(0.3)	11	(0.2)
Dicycloverine	0		3	(0.1)	3	(0.1)
Mebeverine	2	(0.1)	1	(0.1)	3	(0.1)
Mebeverine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Alpha-D-Galactosidase; Simeticone; Trimebutine Maleate	0		1	(0.1)	1	(0.0)
Dicycloverine Hydrochloride	1	(0.1)	0		1	(0.0)
Trimebutine Maleate	0		1	(0.1)	1	(0.0)
Bioflavonoids, C05ca	4	(0.2)	6	(0.3)	10	(0.2)
Diosmin	3	(0.1)	4	(0.2)	7	(0.2)
Arnica Montana; Coumarin; Diosmin; Escin; Sitosterol	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Hesperidin Methyl Chalcone; Ruscus Aculeatus	0		1	(0.1)	1	(0.0)
Diosmin; Hesperidin	0		1	(0.1)	1	(0.0)
Indometacin; Troxerutin	0		1	(0.1)	1	(0.0)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02b	7	(0.3)	3	(0.1)	10	(0.2)
Teprenone	3	(0.1)	3	(0.1)	6	(0.1)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	4	(0.2)	0		4	(0.1)
Epinephrine, C01ca24	2	(0.1)	8	(0.4)	10	(0.2)
Epinephrine	2	(0.1)	7	(0.3)	9	(0.2)
Epinephrine Hydrochloride	0		1	(0.1)	1	(0.0)
Imidazole And Triazole Derivatives, D01ac	6	(0.3)	4	(0.2)	10	(0.2)
Efinaconazole	2	(0.1)	1	(0.1)	3	(0.1)
Luliconazole	2	(0.1)	0		2	(0.1)
Beclometasone Dipropionate; Clotrimazole	0		1	(0.1)	1	(0.0)
Clotrimazole; Hydrocortisone	0		1	(0.1)	1	(0.0)
Econazole Nitrate; Triamcinolone Acetonide	0		1	(0.1)	1	(0.0)
Hydrocortisone; Miconazole Nitrate	1	(0.1)	0		1	(0.0)
Lanoconazole	1	(0.1)	0		1	(0.0)
Papaverine And Derivatives, A03ad	6	(0.3)	4	(0.2)	10	(0.2)
Drotaverine Hydrochloride	3	(0.1)	4	(0.2)	7	(0.2)
Drotaverine	3	(0.1)	0		3	(0.1)
Pertussis Vaccines, J07aj	5	(0.2)	5	(0.2)	10	(0.2)
Diphtheria Vaccine Toxoid; Pertussis Vaccine Acellular; Tetanus Vaccine Toxoid	4	(0.2)	2	(0.1)	6	(0.1)
Diphtheria Vaccine Toxoid; Pertussis Vaccine; Tetanus Vaccine Toxoid	0		2	(0.1)	2	(0.1)
Diphtheria Vaccine Toxoid; Pertussis Vaccine Acellular 3-Component; Tetanus Vaccine Toxoid	1	(0.1)	1	(0.1)	2	(0.1)
Prostaglandin Analogues, S01ee	5	(0.2)	5	(0.2)	10	(0.2)
Latanoprost	4	(0.2)	3	(0.1)	7	(0.2)
Bimatoprost	0		2	(0.1)	2	(0.1)
Tafluprost	1	(0.1)	0		1	(0.0)
Purine Derivatives, C04ad	6	(0.3)	4	(0.2)	10	(0.2)
Pentoxifylline	6	(0.3)	4	(0.2)	10	(0.2)
Trimethoprim And Derivatives, J01ea	4	(0.2)	6	(0.3)	10	(0.2)
Trimethoprim	4	(0.2)	6	(0.3)	10	(0.2)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12, A11db	4	(0.2)	6	(0.3)	10	(0.2)
Cyanocobalamin; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Benfotiamine; Cyanocobalamin; Pyridoxine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Benfotiamine; Pyridoxine Hydrochloride	0		2	(0.1)	2	(0.1)
Pyridoxine Hydrochloride; Thiamine Mononitrate; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Pyridoxine Hydrochloride; Vitamin B1 Nos; Vitamin B12 Nos	1	(0.1)	0		1	(0.0)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	0		1	(0.1)	1	(0.0)
Anticholinergics, R03bb	7	(0.3)	2	(0.1)	9	(0.2)
Ipratropium	2	(0.1)	0		2	(0.1)
Ipratropium Bromide	2	(0.1)	0		2	(0.1)
Umeclidinium Bromide	1	(0.1)	1	(0.1)	2	(0.1)
Tiotropium	1	(0.1)	0		1	(0.0)
Tiotropium Bromide Monohydrate	1	(0.1)	0		1	(0.0)
Umeclidinium	0		1	(0.1)	1	(0.0)
Antiinflammatory Preparations, Non-Steroids For Topical Use, M02aa	7	(0.3)	2	(0.1)	9	(0.2)
Felbinac	5	(0.2)	0		5	(0.1)
Diclofenac Diethylamine; Linum Usitatissimum Seed Oil; Menthol; Methyl Salicylate	1	(0.1)	1	(0.1)	2	(0.1)
Esflurbiprofen; Mentha Spp. Oil	1	(0.1)	0		1	(0.0)
Indometacin; Levomenthol; Tocopheryl Acetate	0		1	(0.1)	1	(0.0)
Combinations Of Various Lipid Modifying Agents, C10ba	3	(0.1)	6	(0.3)	9	(0.2)
Ezetimibe; Rosuvastatin Calcium	2	(0.1)	5	(0.2)	7	(0.2)
Atorvastatin Calcium; Ezetimibe	0		1	(0.1)	1	(0.0)
Fenofibrate; Rosuvastatin	1	(0.1)	0		1	(0.0)
Melatonin Receptor Agonists, N05ch	2	(0.1)	7	(0.3)	9	(0.2)
Melatonin	1	(0.1)	7	(0.3)	8	(0.2)
Ramelteon	1	(0.1)	0		1	(0.0)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids, M01ax	6	(0.3)	3	(0.1)	9	(0.2)
Clonixin Lysinate	2	(0.1)	0		2	(0.1)
Tiaramide Hydrochloride	2	(0.1)	0		2	(0.1)
Angelica Gigas Root; Aronia Melanocarpa Fruit; Ascorbic Acid; Bromelains; Camellia Sinensis Leaf; Chondroitin Sulfate; Curcuma Longa Root; Glucosamine Hydrochloride; Harpagophytum Procumbens Root; Manganese; Me	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Boswellia Serrata; Harpagophytum Procumbens Root; Withania Somnifera Root; Zinc	1	(0.1)	0		1	(0.0)
Diacerein	0		1	(0.1)	1	(0.0)
Glucosamine Sulfate; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	1	(0.1)	0		1	(0.0)
Other Sclerosing Agents, C05bx	6	(0.3)	3	(0.1)	9	(0.2)
Calcium Dobesilate	6	(0.3)	3	(0.1)	9	(0.2)
Tadalafil, G04be08	5	(0.2)	4	(0.2)	9	(0.2)
Tadalafil	5	(0.2)	4	(0.2)	9	(0.2)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Tetanus Vaccines, J07am	6	(0.3)	3	(0.1)	9	(0.2)
Tetanus Vaccine	4	(0.2)	0		4	(0.1)
Tetanus Vaccine Toxoid	2	(0.1)	2	(0.1)	4	(0.1)
Diphtheria Vaccine Toxoid; Tetanus Vaccine Toxoid	0		1	(0.1)	1	(0.0)
Vitamin B-Complex, Plain, A11ea	3	(0.1)	6	(0.3)	9	(0.2)
Vitamin B Complex	3	(0.1)	5	(0.2)	8	(0.2)
Calcium Pantothenate; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Mononitrate	0		1	(0.1)	1	(0.0)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids, R03al	4	(0.2)	4	(0.2)	8	(0.2)
Fenoterol Hydrobromide; Ipratropium Bromide	1	(0.1)	2	(0.1)	3	(0.1)
Beclometasone Dipropionate; Formoterol Fumarate; Glycopyrronium Bromide	0		1	(0.1)	1	(0.0)
Budesonide; Formoterol Fumarate; Glycopyrronium Bromide	1	(0.1)	0		1	(0.0)
Budesonide; Formoterol; Glycopyrronium	0		1	(0.1)	1	(0.0)
Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate	1	(0.1)	0		1	(0.0)
Glycopyrronium Bromide; Indacaterol Maleate	1	(0.1)	0		1	(0.0)
Ipratropium Bromide; Levosalbutamol Sulfate	0		1	(0.1)	1	(0.0)
Umeclidinium Bromide; Vilanterol Trifenatate	0		1	(0.1)	1	(0.0)
Preparations With No Effect On Uric Acid Metabolism, M04ac	5	(0.2)	3	(0.1)	8	(0.2)
Colchicine	5	(0.2)	3	(0.1)	8	(0.2)
Testosterone-5-Alpha Reductase Inhibitors, G04cb	5	(0.2)	3	(0.1)	8	(0.2)
Finasteride	4	(0.2)	2	(0.1)	6	(0.1)
Dutasteride	2	(0.1)	1	(0.1)	3	(0.1)
3-Oxoandrosten (4) Derivatives, G03ba	4	(0.2)	3	(0.1)	7	(0.2)
Testosterone	4	(0.2)	1	(0.1)	5	(0.1)
Testosterone Enanthate	0		1	(0.1)	1	(0.0)
Testosterone Undecylenate	0		1	(0.1)	1	(0.0)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics, C09da	2	(0.1)	5	(0.2)	7	(0.2)
Hydrochlorothiazide; Irbesartan	0		2	(0.1)	2	(0.1)
Hydrochlorothiazide; Losartan Potassium	0		2	(0.1)	2	(0.1)
Hydrochlorothiazide; Valsartan	1	(0.1)	1	(0.1)	2	(0.1)
Candesartan; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Beta Blocking Agents, S01ed	3	(0.1)	4	(0.2)	7	(0.2)
Dorzolamide Hydrochloride; Timolol Maleate	3	(0.1)	2	(0.1)	5	(0.1)
Carteolol Hydrochloride; Latanoprost	0		2	(0.1)	2	(0.1)
Bimatoprost; Timolol Maleate	0		1	(0.1)	1	(0.0)
Bile Acids And Derivatives, A05aa	4	(0.2)	3	(0.1)	7	(0.2)
Ursodeoxycholic Acid	4	(0.2)	3	(0.1)	7	(0.2)
Carbonic Anhydrase Inhibitors, S01ec	1	(0.1)	6	(0.3)	7	(0.2)
Dorzolamide	1	(0.1)	2	(0.1)	3	(0.1)
Brimonidine Tartrate; Brinzolamide	0		2	(0.1)	2	(0.1)
Dorzolamide Hydrochloride	0		2	(0.1)	2	(0.1)
Brinzolamide	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Diazepines, Oxazepines, Thiazepines And Oxepines, N05ah	4	(0.2)	3	(0.1)	7	(0.2)
Quetiapine Fumarate	4	(0.2)	2	(0.1)	6	(0.1)
Olanzapine	0		1	(0.1)	1	(0.0)
Digitalis Glycosides, C01aa	4	(0.2)	3	(0.1)	7	(0.2)
Digoxin	4	(0.2)	3	(0.1)	7	(0.2)
Direct Thrombin Inhibitors, B01ae	4	(0.2)	3	(0.1)	7	(0.2)
Dabigatran Etexilate Mesilate	3	(0.1)	1	(0.1)	4	(0.1)
Dabigatran Etexilate	0		2	(0.1)	2	(0.1)
Dabigatran	1	(0.1)	0		1	(0.0)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia, V03ae	3	(0.1)	4	(0.2)	7	(0.2)
Calcium Polystyrene Sulfonate	2	(0.1)	3	(0.1)	5	(0.1)
Sevelamer	0		1	(0.1)	1	(0.0)
Sodium Zirconium Cyclosilicate	1	(0.1)	0		1	(0.0)
Drugs Used In Nicotine Dependence, N07ba	4	(0.2)	3	(0.1)	7	(0.2)
Nicotine	3	(0.1)	1	(0.1)	4	(0.1)
Nicotine Polacrilex	1	(0.1)	0		1	(0.0)
Varenicline	0		1	(0.1)	1	(0.0)
Varenicline Tartrate	0		1	(0.1)	1	(0.0)
Fenamates, M01ag	3	(0.1)	4	(0.2)	7	(0.2)
Mefenamic Acid	3	(0.1)	4	(0.2)	7	(0.2)
Interleukin Inhibitors, L04ac	4	(0.2)	3	(0.1)	7	(0.2)
Olokizumab	3	(0.1)	0		3	(0.1)
Guselkumab	1	(0.1)	1	(0.1)	2	(0.1)
Netakimab	0		1	(0.1)	1	(0.0)
Tocilizumab	0		1	(0.1)	1	(0.0)
Iron In Other Combinations, B03ae	6	(0.3)	1	(0.1)	7	(0.2)
Ascorbic Acid; Cyanocobalamin; Docusate Sodium; Ferrous Fumarate; Folic Acid; Tocopheryl Acid Succinate	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Colecalciferol; Ferric Pyrophosphate; Folic Acid; Pyridoxine Hydrochloride; Vitamin B12 Nos	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Cyanocobalamin; Folic Acid; Iron	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Ferrous Sulfate; Folic Acid; Protease Nos	1	(0.1)	0		1	(0.0)
Biotin; Calcium Pantothenate; Folic Acid; Iron Pentacarbonyl; Mecobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Vitamin B1 Nos	0		1	(0.1)	1	(0.0)
Cyanocobalamin; Ferrous Fumarate; Folic Acid	1	(0.1)	0		1	(0.0)
Macrolides, J01fa	4	(0.2)	3	(0.1)	7	(0.2)
Roxithromycin	3	(0.1)	2	(0.1)	5	(0.1)
Azithromycin	1	(0.1)	0		1	(0.0)
Spiramycin	0		1	(0.1)	1	(0.0)
Neuraminidase Inhibitors, J05ah	5	(0.2)	2	(0.1)	7	(0.2)
Oseltamivir Phosphate	3	(0.1)	1	(0.1)	4	(0.1)
Oseltamivir	2	(0.1)	1	(0.1)	3	(0.1)
Other Alimentary Tract And Metabolism Products, A16a	4	(0.2)	3	(0.1)	7	(0.2)
Clostridium Butyricum	4	(0.2)	3	(0.1)	7	(0.2)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Immunosuppressants, L04ax	3	(0.1)	4	(0.2)	7	(0.2)
Methotrexate	3	(0.1)	3	(0.1)	6	(0.1)
Methotrexate Sodium	0		1	(0.1)	1	(0.0)
Other Intestinal Antiinfectives, A07ax	2	(0.1)	5	(0.2)	7	(0.2)
Nifuroxazide	1	(0.1)	4	(0.2)	5	(0.1)
Berberine Hydrochloride; Geranium Thunbergii Herb	1	(0.1)	1	(0.1)	2	(0.1)
Other Urologicals, G04bx	4	(0.2)	3	(0.1)	7	(0.2)
Phenazopyridine	2	(0.1)	2	(0.1)	4	(0.1)
Phenazopyridine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Other Vasodilators Used In Cardiac Diseases, C01dx	4	(0.2)	3	(0.1)	7	(0.2)
Sacubitril	3	(0.1)	2	(0.1)	5	(0.1)
Ligustrazine	0		1	(0.1)	1	(0.0)
Nicorandil	1	(0.1)	0		1	(0.0)
Preparations With Salicylic Acid Derivatives, M02ac	2	(0.1)	5	(0.2)	7	(0.2)
Diethylamine Salicylate	1	(0.1)	3	(0.1)	4	(0.1)
Camphor; Capsicum Spp. Extract; Methyl Salicylate	1	(0.1)	0		1	(0.0)
Camphor; Enoxolone; Eucalyptus Globulus Oil; Glycol Salicylate; Menthol; Methyl Salicylate	0		1	(0.1)	1	(0.0)
Trolamine Salicylate	0		1	(0.1)	1	(0.0)
Synthetic Anticholinergics, Quaternary Ammonium Compounds, A03ab	4	(0.2)	3	(0.1)	7	(0.2)
Otilonium Bromide	2	(0.1)	1	(0.1)	3	(0.1)
Pipoxolan Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Timepidium Bromide	1	(0.1)	0		1	(0.0)
Ace Inhibitors And Calcium Channel Blockers, C09bb	1	(0.1)	5	(0.2)	6	(0.1)
Amlodipine Besilate; Perindopril Erbumine	0		2	(0.1)	2	(0.1)
Amlodipine Besilate; Ramipril	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Benazepril Hydrochloride	0		1	(0.1)	1	(0.0)
Amlodipine; Benazepril	0		1	(0.1)	1	(0.0)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers, C09db	3	(0.1)	3	(0.1)	6	(0.1)
Amlodipine Besilate; Telmisartan	0		2	(0.1)	2	(0.1)
Amlodipine Besilate; Azilsartan	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Irbesartan	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Valsartan	1	(0.1)	0		1	(0.0)
Amlodipine; Valsartan	0		1	(0.1)	1	(0.0)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations, C09dx	3	(0.1)	3	(0.1)	6	(0.1)
Sacubitril; Valsartan	3	(0.1)	3	(0.1)	6	(0.1)
Antidiarrheal Microorganisms, A07f	5	(0.2)	1	(0.1)	6	(0.1)
Antidiarrheal Microorganisms	5	(0.2)	1	(0.1)	6	(0.1)
Beta-Lactamase Sensitive Penicillins, J01ce	3	(0.1)	3	(0.1)	6	(0.1)
Phenoxymethylpenicillin	2	(0.1)	2	(0.1)	4	(0.1)
Phenoxymethylpenicillin Potassium	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Calcium, Combinations With Vitamin D And/Or Other Drugs, A12ax	5	(0.2)	1	(0.1)	6	(0.1)
Calcium Carbonate; Colecalciferol	3	(0.1)	1	(0.1)	4	(0.1)
Calcium Carbonate; Colecalciferol; Menaquinone	1	(0.1)	0		1	(0.0)
Calcium Phosphate; Calcium Sodium Lactate; Ergocalciferol	1	(0.1)	0		1	(0.0)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds, A02ad	2	(0.1)	4	(0.2)	6	(0.1)
Aluminium Hydroxide; Magnesium Hydroxide	0		2	(0.1)	2	(0.1)
Aluminium Hydroxide Gel; Magnesium Hydroxide	0		1	(0.1)	1	(0.0)
Aluminium Magnesium Silicate	0		1	(0.1)	1	(0.0)
Calcium Carbonate; Calcium Phosphate; Kaolin; Magnesium Carbonate; Magnesium Hydroxide; Magnesium Oxide	1	(0.1)	0		1	(0.0)
Hydrotalcite	1	(0.1)	0		1	(0.0)
Corticosteroids For Systemic Use, Combinations, H02bx	3	(0.1)	3	(0.1)	6	(0.1)
Betamethasone; Dexchlorpheniramine Maleate	2	(0.1)	2	(0.1)	4	(0.1)
Betamethasone Acetate; Sodium Phosphate Dibasic	1	(0.1)	0		1	(0.0)
Betamethasone; Chlorphenamine Maleate	0		1	(0.1)	1	(0.0)
Enzymes, C04af	1	(0.1)	5	(0.2)	6	(0.1)
Kallidinogenase	1	(0.1)	5	(0.2)	6	(0.1)
Fourth-Generation Cephalosporins, J01de	4	(0.2)	2	(0.1)	6	(0.1)
Cefepime	2	(0.1)	1	(0.1)	3	(0.1)
Cefepime Hydrochloride	2	(0.1)	0		2	(0.1)
Cefepime Hydrochloride; Sulbactam Sodium	0		1	(0.1)	1	(0.0)
Cefozopran Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antidiarrheals, A07xa	3	(0.1)	3	(0.1)	6	(0.1)
Albumin Tannate	1	(0.1)	2	(0.1)	3	(0.1)
Chloroform And Morphine Tincture; Kaolin; Pectin; Potassium Chloride; Sodium Chloride; Sodium Lactate	1	(0.1)	0		1	(0.0)
Citrus Aurantium Peel; Creosote; Glycyrrhiza Spp. Root; Phellodendron Spp. Bark; Uncaria Gambir Leaf With Twig	1	(0.1)	0		1	(0.0)
Racecadotril	0		1	(0.1)	1	(0.0)
Other Antiepileptics, N03ax	5	(0.2)	1	(0.1)	6	(0.1)
Topiramate	3	(0.1)	1	(0.1)	4	(0.1)
Levetiracetam	2	(0.1)	0		2	(0.1)
Other Capillary Stabilizing Agents, C05cx	2	(0.1)	4	(0.2)	6	(0.1)
Hesperidin	2	(0.1)	1	(0.1)	3	(0.1)
Escin	0		1	(0.1)	1	(0.0)
Escin Sodium	0		1	(0.1)	1	(0.0)
Hesperidin Methyl Chalcone	0		1	(0.1)	1	(0.0)
Other Cold Preparations, R05x	2	(0.1)	4	(0.2)	6	(0.1)
Ascorbic Acid; Gentiana Lutea Root; Primula Spp. Flower; Rumex Acetosa; Sambucus Nigra Flower; Verbena Officinalis Herb	1	(0.1)	3	(0.1)	4	(0.1)
Camphor; Eucalyptus Globulus Oil; Juniperus Virginiana Wood Oil; Menthol; Myristica Fragrans Oil; Pinus Nigra Oil; Thymol	0		1	(0.1)	1	(0.0)
Honey; Plantago Lanceolata Fluid Extract; Thymus Serpyllum Fluid Extract; Thymus Vulgaris Fluid Extract	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Hypnotics And Sedatives, N05cm	3	(0.1)	3	(0.1)	6	(0.1)
Dexmedetomidine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Suvorexant	1	(0.1)	1	(0.1)	2	(0.1)
Bromisoval	0		1	(0.1)	1	(0.0)
Lemborexant	1	(0.1)	0		1	(0.0)
Oxazol, Thiazine, And Triazine Derivatives, M03bb	4	(0.2)	2	(0.1)	6	(0.1)
Chlorzoxazone	3	(0.1)	1	(0.1)	4	(0.1)
Chlorzoxazone; Ibuprofen; Paracetamol	0		1	(0.1)	1	(0.0)
Metaxalone	1	(0.1)	0		1	(0.0)
Progestogens, G03ac	4	(0.2)	2	(0.1)	6	(0.1)
Desogestrel	1	(0.1)	0		1	(0.0)
Drospirenone	1	(0.1)	0		1	(0.0)
Ethinylestradiol; Ferrous Fumarate; Norethisterone Acetate	0		1	(0.1)	1	(0.0)
Ethinylestradiol; Levonorgestrel	1	(0.1)	0		1	(0.0)
Etonogestrel	0		1	(0.1)	1	(0.0)
Medroxyprogesterone	1	(0.1)	0		1	(0.0)
Norethisterone	1	(0.1)	0		1	(0.0)
Norethisterone Acetate	1	(0.1)	0		1	(0.0)
Pyrethrines, Incl. Synthetic Compounds, P03ac	2	(0.1)	4	(0.2)	6	(0.1)
Permethrin	2	(0.1)	4	(0.2)	6	(0.1)
Viral Vaccines, J07b	1	(0.1)	5	(0.2)	6	(0.1)
Viral Vaccines	1	(0.1)	5	(0.2)	6	(0.1)
Xanthines, R03da	1	(0.1)	5	(0.2)	6	(0.1)
Aminophylline	0		2	(0.1)	2	(0.1)
Diprophylline	1	(0.1)	1	(0.1)	2	(0.1)
Ambroxol Acefyllinate	0		1	(0.1)	1	(0.0)
Doxofylline	0		1	(0.1)	1	(0.0)
Ace Inhibitors And Diuretics, C09ba	3	(0.1)	2	(0.1)	5	(0.1)
Hydrochlorothiazide; Ramipril	0		2	(0.1)	2	(0.1)
Captopril; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Lisinopril	1	(0.1)	0		1	(0.0)
Indapamide; Perindopril Erbumine	1	(0.1)	0		1	(0.0)
Adrenergic And Dopaminergic Agents, C01ca	3	(0.1)	2	(0.1)	5	(0.1)
Norepinephrine	1	(0.1)	1	(0.1)	2	(0.1)
Dopamine	1	(0.1)	0		1	(0.0)
Dopamine Hydrochloride	0		1	(0.1)	1	(0.0)
Midodrine Hydrochloride	1	(0.1)	0		1	(0.0)
Norepinephrine Bitartrate	0		1	(0.1)	1	(0.0)
Alpha- And Beta-Adrenoreceptor Agonists, R03ca	0		5	(0.2)	5	(0.1)
Methylephedrine Hydrochloride-Dl	0		5	(0.2)	5	(0.1)
Antiarrhythmics, Class Ic, C01bc	5	(0.2)	0		5	(0.1)
Propafenone Hydrochloride	3	(0.1)	0		3	(0.1)
Flecainide Acetate	1	(0.1)	0		1	(0.0)
Pilsicainide Hydrochloride	1	(0.1)	0		1	(0.0)
Antiinfectives For Treatment Of Acne, D10af	2	(0.1)	3	(0.1)	5	(0.1)
Nadifloxacin	1	(0.1)	3	(0.1)	4	(0.1)
Benzoyl Peroxide; Clindamycin Phosphate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Antiseptics, R02aa	3	(0.1)	2	(0.1)	5	(0.1)
Amylmetacresol; Dichlorobenzyl Alcohol	2	(0.1)	0		2	(0.1)
Amylmetacresol; Dichlorobenzyl Alcohol; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Benzoxonium Chloride; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Dichlorobenzyl Alcohol	1	(0.1)	0		1	(0.0)
Azaspirodecanedione Derivatives, N05be	3	(0.1)	2	(0.1)	5	(0.1)
Buspirone	3	(0.1)	1	(0.1)	4	(0.1)
Buspirone Hydrochloride	0		1	(0.1)	1	(0.0)
Hydrazinophthalazine Derivatives, C02db	3	(0.1)	2	(0.1)	5	(0.1)
Hydralazine	3	(0.1)	2	(0.1)	5	(0.1)
Local Anesthetics, S01ha	1	(0.1)	4	(0.2)	5	(0.1)
Proxymetacaine Hydrochloride	1	(0.1)	3	(0.1)	4	(0.1)
Benzalkonium Chloride; Lidocaine Hydrochloride; Methylcellulose	0		1	(0.1)	1	(0.0)
Multivitamins With Minerals, A11aa	1	(0.1)	4	(0.2)	5	(0.1)
Ascorbic Acid; Betacarotene; Bioflavonoids Nos; Chromium; Copper; Cystine; Folic Acid; Iodine; Iron; Levocarnitine; Magnesium; Manganese; Menadione; Nicotinic Acid; Pantothenic Acid; Pyridoxine Hydrochloride; Retinol	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Biotin; Calcium Pantothenate; Calcium Phosphate Dibasic; Chromic Chloride; Colecalciferol; Cupric Oxide; Ferrous Sulfate; Folic Acid; Magnesium Oxide; Manganese Chloride; Mecobalamin; Nicotinamide;	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium; Colecalciferol; Copper; Cyanocobalamin; Folic Acid; Iron; Nicotinamide; Pyridoxine Hydrochloride; Retinol; Riboflavin; Thiamine Hydrochloride; Tocopherol; Zinc	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Chromium; Copper; Cyanocobalamin; Folic Acid; Iodine; Magnesium; Manganese; Molybdenum; Nicotinic Acid; Pantothenic Acid; Potassium; Pyridoxine Hydrochloride; Retinol; Riboflavin; Selenium; Thiamine; To	0		1	(0.1)	1	(0.0)
Multivitamins With Minerals [Umbrella Term]	0		1	(0.1)	1	(0.0)
Nasal Decongestants For Systemic Use, R01b	4	(0.2)	1	(0.1)	5	(0.1)
Nasal Decongestants For Systemic Use	4	(0.2)	1	(0.1)	5	(0.1)
Natural And Semisynthetic Estrogens, Plain, G03ca	3	(0.1)	2	(0.1)	5	(0.1)
Estradiol	2	(0.1)	0		2	(0.1)
Estradiol Hemihydrate; Norethisterone Acetate	0		1	(0.1)	1	(0.0)
Estradiol; Norethisterone Acetate	1	(0.1)	0		1	(0.0)
Estriol	0		1	(0.1)	1	(0.0)
Other Antibiotics For Topical Use, D06ax	1	(0.1)	4	(0.2)	5	(0.1)
Bacitracin Zinc; Lidocaine; Neomycin Sulfate; Polymyxin B Sulfate	0		1	(0.1)	1	(0.0)
Bacitracin; Colistin Sulfate	0		1	(0.1)	1	(0.0)
Chloramphenicol; Methyluracil	0		1	(0.1)	1	(0.0)
Hinokitiol	0		1	(0.1)	1	(0.0)
Lidocaine Hydrochloride; Primycin Sulfate	1	(0.1)	0		1	(0.0)
Other Antipsychotics, N05ax	3	(0.1)	2	(0.1)	5	(0.1)
Aripiprazole	2	(0.1)	1	(0.1)	3	(0.1)
Cariprazine	0		1	(0.1)	1	(0.0)
Prothipendyl	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Drugs For Constipation, A06ax	2	(0.1)	3	(0.1)	5	(0.1)
Elobixibat	1	(0.1)	1	(0.1)	2	(0.1)
Linaclotide	1	(0.1)	1	(0.1)	2	(0.1)
Lubiprostone	0		1	(0.1)	1	(0.0)
Other Immunostimulants, L03ax	1	(0.1)	4	(0.2)	5	(0.1)
Arabinogalactan; Ascorbic Acid; Beta Glucan; Calcium Carbonate; Calcium Pantothenate; Calcium Phosphate; Calcium Phosphate Monobasic; Chromium Picolinate; Colecalciferol; Cyanocobalamin; Folic Acid; Magnesium Ca	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Colecalciferol; Selenium; Zinc	1	(0.1)	0		1	(0.0)
Luminol Sodium	0		1	(0.1)	1	(0.0)
Meglumine Acridonacetate	0		1	(0.1)	1	(0.0)
Transfer Factor	0		1	(0.1)	1	(0.0)
Other Intestinal Adsorbents, A07bc	2	(0.1)	3	(0.1)	5	(0.1)
Diosmectite	1	(0.1)	1	(0.1)	2	(0.1)
Gelatin Tannate	0		1	(0.1)	1	(0.0)
Kaolin	1	(0.1)	0		1	(0.0)
Polymethylsiloxane Polyhydrate	0		1	(0.1)	1	(0.0)
Other Systemic Hemostatics, B02bx	4	(0.2)	1	(0.1)	5	(0.1)
Carbazochrome Sodium Sulfonate	3	(0.1)	1	(0.1)	4	(0.1)
Carbazochrome	1	(0.1)	0		1	(0.0)
Etamsilate	1	(0.1)	0		1	(0.0)
Phenothiazine Derivatives, R06ad	0		5	(0.2)	5	(0.1)
Promethazine Methylene Disalicylate	0		4	(0.2)	4	(0.1)
Thiethylperazine Maleate	0		1	(0.1)	1	(0.0)
Phenylalkylamine Derivatives, C08da	3	(0.1)	2	(0.1)	5	(0.1)
Verapamil Hydrochloride	3	(0.1)	1	(0.1)	4	(0.1)
Verapamil	0		1	(0.1)	1	(0.0)
Pyrimidine Analogues, L01bc	3	(0.1)	2	(0.1)	5	(0.1)
Capecitabine	1	(0.1)	1	(0.1)	2	(0.1)
Fluorouracil	2	(0.1)	0		2	(0.1)
Gemcitabine	0		1	(0.1)	1	(0.0)
Selective Immunosuppressants, L04aa	3	(0.1)	2	(0.1)	5	(0.1)
Baricitinib	1	(0.1)	1	(0.1)	2	(0.1)
Iguratimod	1	(0.1)	0		1	(0.0)
Tofacitinib	0		1	(0.1)	1	(0.0)
Tofacitinib Citrate	1	(0.1)	0		1	(0.0)
Selective Serotonin (5ht1) Agonists, N02cc	1	(0.1)	4	(0.2)	5	(0.1)
Eletriptan Hydrobromide	0		1	(0.1)	1	(0.0)
Naratriptan	0		1	(0.1)	1	(0.0)
Rizatriptan	0		1	(0.1)	1	(0.0)
Sumatriptan	1	(0.1)	0		1	(0.0)
Sumatriptan Succinate	0		1	(0.1)	1	(0.0)
Tonics, A13a	2	(0.1)	3	(0.1)	5	(0.1)
Dietary Supplement	2	(0.1)	1	(0.1)	3	(0.1)
Oxyethylammonium Methylphenoxyacetate	0		2	(0.1)	2	(0.1)
Vitamin K Antagonists, B01aa	2	(0.1)	3	(0.1)	5	(0.1)
Warfarin	2	(0.1)	2	(0.1)	4	(0.1)
Warfarin Sodium	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamins With Minerals, A11jb	4	(0.2)	1	(0.1)	5	(0.1)
Vitamins With Minerals	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Biotin; Copper; Retinol; Zinc	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium Carbonate; Calcium Pantothenate; Calcium Phosphate; Chromium; Cyanocobalamin; Folic Acid; Magnesium Carbonate; Magnesium Hydroxide; Manganese Gluconate; Nicotinic Acid; Potassium Bicarbona	1	(0.1)	0		1	(0.0)
Vitamins Nos; Zinc Sulfate	1	(0.1)	0		1	(0.0)
Anticholinesterases, N06da	0		4	(0.2)	4	(0.1)
Ipidacrine	0		3	(0.1)	3	(0.1)
Donepezil Hydrochloride	0		1	(0.1)	1	(0.0)
Rivastigmine	0		1	(0.1)	1	(0.0)
Aromatase Inhibitors, L02bg	1	(0.1)	3	(0.1)	4	(0.1)
Anastrozole	1	(0.1)	1	(0.1)	2	(0.1)
Letrozole	0		2	(0.1)	2	(0.1)
Benzodiazepine Derivatives, N03ae	1	(0.1)	3	(0.1)	4	(0.1)
Clonazepam	1	(0.1)	3	(0.1)	4	(0.1)
Beta-Lactamase Resistant Penicillins, J01cf	2	(0.1)	2	(0.1)	4	(0.1)
Flucloxacillin	1	(0.1)	1	(0.1)	2	(0.1)
Cloxacillin	0		1	(0.1)	1	(0.0)
Dicloxacillin	1	(0.1)	0		1	(0.0)
Dicloxacillin Sodium Monohydrate	1	(0.1)	0		1	(0.0)
Corticosteroids, Moderately Potent (Group Ii), D07ab	1	(0.1)	3	(0.1)	4	(0.1)
Dexamethasone Propionate	1	(0.1)	3	(0.1)	4	(0.1)
Corticosteroids, Potent, Combinations With Antibiotics, D07cc	2	(0.1)	2	(0.1)	4	(0.1)
Betamethasone Valerate; Fusidic Acid	1	(0.1)	1	(0.1)	2	(0.1)
Betamethasone Valerate; Clioquinol; Gentamicin Sulfate; Tolnaftate	1	(0.1)	0		1	(0.0)
Clotrimazole; Fusidic Acid; Mometasone	0		1	(0.1)	1	(0.0)
Corticosteroids, Weak, Combinations With Antibiotics, D07ca	1	(0.1)	3	(0.1)	4	(0.1)
Diphenhydramine Hydrochloride; Hydrocortisone Acetate; Neomycin Sulfate	0		2	(0.1)	2	(0.1)
Chloramphenicol; Neomycin Sulfate; Prednisolone	1	(0.1)	0		1	(0.0)
Hydrocortisone; Natamycin; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Dopamine Agonists, N04bc	2	(0.1)	2	(0.1)	4	(0.1)
Pramipexole Dihydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Pramipexole	1	(0.1)	0		1	(0.0)
Ropinirole Hydrochloride	0		1	(0.1)	1	(0.0)
Electrolyte Solutions, B05xa	1	(0.1)	3	(0.1)	4	(0.1)
Electrolyte Solutions [Umbrella Term]	1	(0.1)	3	(0.1)	4	(0.1)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting, A10ad	0		4	(0.2)	4	(0.1)
Insulin	0		1	(0.1)	1	(0.0)
Insulin Aspart; Insulin Degludec	0		1	(0.1)	1	(0.0)
Insulin Human; Insulin Human Injection, Isophane	0		1	(0.1)	1	(0.0)
Insulin; Isophane Insulin	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Agents For Local Oral Treatment, A01ad	3	(0.1)	1	(0.1)	4	(0.1)
Butyl Aminobenzoate; Eugenol; Iodoform	0		1	(0.1)	1	(0.0)
Cetrimide; Lidocaine; Tannic Acid; Zinc Chloride	1	(0.1)	0		1	(0.0)
Rheum Spp.; Salicylic Acid	1	(0.1)	0		1	(0.0)
Sodium Bicarbonate; Sodium Chloride	1	(0.1)	0		1	(0.0)
Other Analgesics And Antipyretics, N02bg	2	(0.1)	2	(0.1)	4	(0.1)
Mirogabalin Besilate	1	(0.1)	2	(0.1)	3	(0.1)
Nefopam	1	(0.1)	0		1	(0.0)
Other Antipsoriatics For Topical Use, D05ax	1	(0.1)	3	(0.1)	4	(0.1)
Betamethasone Dipropionate; Calcipotriol	0		2	(0.1)	2	(0.1)
Betamethasone Dipropionate; Calcipotriol Monohydrate	1	(0.1)	0		1	(0.0)
Calcipotriol	0		1	(0.1)	1	(0.0)
Calcipotriol Monohydrate	0		1	(0.1)	1	(0.0)
Platinum Compounds, L01xa	3	(0.1)	1	(0.1)	4	(0.1)
Oxaliplatin	3	(0.1)	0		3	(0.1)
Carboplatin	0		1	(0.1)	1	(0.0)
Sulfur-Containing Imidazole Derivatives, H03bb	0		4	(0.2)	4	(0.1)
Thiamazole	0		4	(0.2)	4	(0.1)
Antidotes, V03ab	1	(0.1)	2	(0.1)	3	(0.1)
Flumazenil	1	(0.1)	1	(0.1)	2	(0.1)
Sugammadex Sodium	0		1	(0.1)	1	(0.0)
Benzothiazepine Derivatives, C08db	1	(0.1)	2	(0.1)	3	(0.1)
Diltiazem Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Diltiazem	0		1	(0.1)	1	(0.0)
Carbapenems, J01dh	0		3	(0.1)	3	(0.1)
Meropenem	0		2	(0.1)	2	(0.1)
Ertapenem Sodium	0		1	(0.1)	1	(0.0)
Meropenem Trihydrate	0		1	(0.1)	1	(0.0)
Corticosteroids For Systemic Use, H02	2	(0.1)	1	(0.1)	3	(0.1)
Steroids	2	(0.1)	0		2	(0.1)
Corticosteroids	0		1	(0.1)	1	(0.0)
Corticosteroids, C05aa	1	(0.1)	2	(0.1)	3	(0.1)
Escherichia Coli; Hydrocortisone	1	(0.1)	1	(0.1)	2	(0.1)
Cinchocaine Hydrochloride; Menthol; Prednisolone; Ruscogenin; Zinc Oxide	0		1	(0.1)	1	(0.0)
Diflucortolone Valerate; Lidocaine	0		1	(0.1)	1	(0.0)
Enzymes, B01ad	1	(0.1)	2	(0.1)	3	(0.1)
Alteplase	0		2	(0.1)	2	(0.1)
Hydroxytyrosol; Nattokinase	1	(0.1)	0		1	(0.0)
Ethers, Chemically Close To Antihistamines, M03bc	1	(0.1)	2	(0.1)	3	(0.1)
Diclofenac Sodium; Orphenadrine Citrate	1	(0.1)	0		1	(0.0)
Orphenadrine	0		1	(0.1)	1	(0.0)
Orphenadrine Citrate	0		1	(0.1)	1	(0.0)
Fatty Acid Derivatives, N03ag	0		3	(0.1)	3	(0.1)
Valproate Sodium	0		2	(0.1)	2	(0.1)
Gamma-Aminobutyric Acid; Nicotinic Acid	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Fluoroquinolones, J01ma	2	(0.1)	1	(0.1)	3	(0.1)
Garenoxacin Mesilate	1	(0.1)	0		1	(0.0)
Gemifloxacin Mesilate	0		1	(0.1)	1	(0.0)
Pefloxacin	1	(0.1)	0		1	(0.0)
Glycogenolytic Hormones, H04aa	1	(0.1)	2	(0.1)	3	(0.1)
Glucagon	1	(0.1)	2	(0.1)	3	(0.1)
Halogenated Hydrocarbons, N01ab	1	(0.1)	2	(0.1)	3	(0.1)
Sevoflurane	0		2	(0.1)	2	(0.1)
Desflurane	1	(0.1)	0		1	(0.0)
Hepatitis Vaccines, J07bc	1	(0.1)	2	(0.1)	3	(0.1)
Hepatitis B Vaccine	0		2	(0.1)	2	(0.1)
Hepatitis A Vaccine Inact; Hepatitis B Vaccine Rhbsag (Yeast)	1	(0.1)	0		1	(0.0)
Homeopathic Preparation, V91	1	(0.1)	2	(0.1)	3	(0.1)
Bradykinin Antibodies; Histamin Antibodies; Morphine Antibodies	1	(0.1)	2	(0.1)	3	(0.1)
Liver Therapy, A05ba	1	(0.1)	2	(0.1)	3	(0.1)
Phospholipids Soybean	1	(0.1)	1	(0.1)	2	(0.1)
Inosine; Meglumine; Methionine; Nicotinamide; Succinic Acid	0		1	(0.1)	1	(0.0)
Measles Vaccines, J07bd	0		3	(0.1)	3	(0.1)
Measles Vaccine Live; Rubella Vaccine Live	0		1	(0.1)	1	(0.0)
Measles Vaccine; Mumps Vaccine; Rubella Vaccine	0		1	(0.1)	1	(0.0)
Measles Vaccine; Rubella Vaccine	0		1	(0.1)	1	(0.0)
Multivitamins, Other Combinations, A11ab	1	(0.1)	2	(0.1)	3	(0.1)
Ascorbic Acid; Betacarotene; Biotin; Calcium; Carbohydrates Nos; Chloride; Choline; Chromium; Copper; Cyanocobalamin; Fats Nos; Fibre, Dietary; Fluorine; Folic Acid; Iodine; Iron; Magnesium; Manganese; Molybdenum; Nicot	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Ergocalciferol; Folic Acid; Nicotinamide; Panthenol; Retinol; Riboflavin; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Multivitamins, Other Combinations	1	(0.1)	0		1	(0.0)
Opioid Anesthetics, N01ah	0		3	(0.1)	3	(0.1)
Alfentanil Hydrochloride	0		1	(0.1)	1	(0.0)
Remifentanil	0		1	(0.1)	1	(0.0)
Remifentanil Hydrochloride	0		1	(0.1)	1	(0.0)
Other Anti-Acne Preparations For Topical Use, D10ax	1	(0.1)	2	(0.1)	3	(0.1)
Azelaic Acid	1	(0.1)	1	(0.1)	2	(0.1)
Acetone; Acid Fuchsin; Boric Acid; Ethanol; Phenol; Resorcinol	0		1	(0.1)	1	(0.0)
Other Antifungals For Topical Use, D01ae	2	(0.1)	1	(0.1)	3	(0.1)
Fenticlor	0		1	(0.1)	1	(0.0)
Naftifine Hydrochloride	1	(0.1)	0		1	(0.0)
Tolnaftate	1	(0.1)	0		1	(0.0)
Other Antiinfectives, S01ax	0		3	(0.1)	3	(0.1)
Iodine; Polyvinyl Alcohol	0		2	(0.1)	2	(0.1)
Picloxydine	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Drugs Affecting Bone Structure And Mineralization, M05bx	2	(0.1)	1	(0.1)	3	(0.1)
Denosumab	2	(0.1)	1	(0.1)	3	(0.1)
Other Parasympathomimetics, N07ax	2	(0.1)	1	(0.1)	3	(0.1)
Choline Alfoscerate	2	(0.1)	1	(0.1)	3	(0.1)
Other Quinolones, J01mb	2	(0.1)	1	(0.1)	3	(0.1)
Nalidixic Acid	2	(0.1)	1	(0.1)	3	(0.1)
Rabies Vaccines, J07bg	0		3	(0.1)	3	(0.1)
Rabies Vaccine	0		1	(0.1)	1	(0.0)
Rabies Vaccine Inact (Chick Embryo)	0		1	(0.1)	1	(0.0)
Rabies Vaccine Inact (Vero)	0		1	(0.1)	1	(0.0)
Solutions For Parenteral Nutrition, B05ba	1	(0.1)	2	(0.1)	3	(0.1)
Amino Acids Nos; Calcium Chloride; Electrolytes Nos; Glucose; Lipids Nos	0		1	(0.1)	1	(0.0)
Amino Acids Nos; Electrolytes Nos; Glucose; Thiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Amino Acids Nos; Glucose; Lipids Nos	0		1	(0.1)	1	(0.0)
Substituted Alkylamines, R06ab	2	(0.1)	1	(0.1)	3	(0.1)
Dexchlorpheniramine	1	(0.1)	1	(0.1)	2	(0.1)
Dexchlorpheniramine Maleate	1	(0.1)	0		1	(0.0)
Triazole Derivatives, J02ac	2	(0.1)	1	(0.1)	3	(0.1)
Itraconazole	2	(0.1)	1	(0.1)	3	(0.1)
Vitamin B-Complex With Vitamin C, A11eb	2	(0.1)	1	(0.1)	3	(0.1)
Ascorbic Acid; Dexpanthenol; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Biotin; Calcium Pantothenate; Folic Acid; Nicotinamide; Nicotinic Acid; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Vitamin D Tablet, A11cc04	0		3	(0.1)	3	(0.1)
Calcitriol	0		3	(0.1)	3	(0.1)
Ace Inhibitors, Other Combinations, C09bx	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Indapamide; Perindopril Arginine	1	(0.1)	1	(0.1)	2	(0.1)
Agents For Dermatitis, Excluding Corticosteroids, D11ah	1	(0.1)	1	(0.1)	2	(0.1)
Delgocitinib	0		1	(0.1)	1	(0.0)
Pimecrolimus	1	(0.1)	0		1	(0.0)
Aldose Reductase Inhibitors, A10xa	1	(0.1)	1	(0.1)	2	(0.1)
Epalrestat	1	(0.1)	1	(0.1)	2	(0.1)
Antacids With Antiflatulents, A02af	2	(0.1)	0		2	(0.1)
Aluminium Hydroxide; Dicycloverine Hydrochloride; Magnesium Oxide; Simeticone	1	(0.1)	0		1	(0.0)
Aluminium Hydroxide; Magnesium Hydroxide; Simeticone	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Antacids With Sodium Bicarbonate, A02ah	1	(0.1)	1	(0.1)	2	(0.1)
Acorus Calamus Var. Angustatus Rhizome; Bismuth Subnitrate; Citrus Aurantium Fruit Peel; Glycyrrhiza Spp. Root With Rhizome; Magnesium Carbonate; Magnesium Oxide; Rheum Spp. Root With Rhizome; Sodium Bicarbo	0		1	(0.1)	1	(0.0)
Acorus Calamus; Bismuth Subnitrate; Magnesium Carbonate; Rhamnus Frangula; Sodium Bicarbonate	1	(0.1)	0		1	(0.0)
Antacids, A02a	1	(0.1)	1	(0.1)	2	(0.1)
Antacids	1	(0.1)	1	(0.1)	2	(0.1)
Antibiotics, R02ab	2	(0.1)	0		2	(0.1)
Benzalkonium Chloride; Benzocaine; Tyrothricin	1	(0.1)	0		1	(0.0)
Cetylpyridinium Chloride; Gramicidin S Hydrochloride	1	(0.1)	0		1	(0.0)
Antiinfectives And Antiseptics For Local Oral Treatment, A01ab	2	(0.1)	0		2	(0.1)
Benzydamine Hydrochloride; Chlorhexidine Gluconate	1	(0.1)	0		1	(0.0)
Sodium Perborate Monohydrate	1	(0.1)	0		1	(0.0)
Bacterial And Viral Vaccines, Combined, J07ca	1	(0.1)	1	(0.1)	2	(0.1)
Diphtheria Vaccine Toxoid; Pertussis Vaccine Acellular 3-Component; Polio Vaccine Inact 3v (Vero); Tetanus Vaccine Toxoid	0		1	(0.1)	1	(0.0)
Diphtheria Vaccine; Pertussis Vaccine; Polio Vaccine; Tetanus Vaccine	1	(0.1)	0		1	(0.0)
Benzimidazole Derivatives, P02ca	1	(0.1)	1	(0.1)	2	(0.1)
Albendazole	1	(0.1)	1	(0.1)	2	(0.1)
Biguanides, P01bb	1	(0.1)	1	(0.1)	2	(0.1)
Atovaquone; Proguanil	0		1	(0.1)	1	(0.0)
Proguanil Hydrochloride	1	(0.1)	0		1	(0.0)
Bile Acid Sequestrants, C10ac	1	(0.1)	1	(0.1)	2	(0.1)
Colesevelam Hydrochloride	0		1	(0.1)	1	(0.0)
Colestipol Hydrochloride	1	(0.1)	0		1	(0.0)
Blood Substitutes And Perfusion Solutions, B05	2	(0.1)	0		2	(0.1)
Carbohydrates Nos; Potassium Chloride; Sodium Chloride; Sodium Lactate	2	(0.1)	0		2	(0.1)
Calcitonin Gene-Related Peptide (Cgrp) Antagonists, N02cd	1	(0.1)	1	(0.1)	2	(0.1)
Erenumab	0		1	(0.1)	1	(0.0)
Ubrogepant	1	(0.1)	0		1	(0.0)
Centrally Acting Sympathomimetics, N06ba	1	(0.1)	1	(0.1)	2	(0.1)
Amfetamine Aspartate; Amfetamine Sulfate; Dexamfetamine Saccharate; Dexamfetamine Sulfate	1	(0.1)	1	(0.1)	2	(0.1)
Colony Stimulating Factors, L03aa	2	(0.1)	0		2	(0.1)
Filgrastim	1	(0.1)	0		1	(0.0)
Pegfilgrastim	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Combinations For Eradication Of Helicobacter Pylori, A02bd	1	(0.1)	1	(0.1)	2	(0.1)
Amoxicillin Trihydrate; Clarithromycin; Vonoprazan Fumarate	1	(0.1)	1	(0.1)	2	(0.1)
Amoxicillin Trihydrate; Metronidazole; Vonoprazan Fumarate	0		1	(0.1)	1	(0.0)
Combinations Of Antibacterials, J01ra	2	(0.1)	0		2	(0.1)
Azithromycin; Bacillus Coagulans; Cefixime	1	(0.1)	0		1	(0.0)
Cefixime; Ofloxacin	1	(0.1)	0		1	(0.0)
Combinations Of Oral Blood Glucose Lowering Drugs, A10bd	1	(0.1)	1	(0.1)	2	(0.1)
Glibenclamide; Metformin Hydrochloride	1	(0.1)	0		1	(0.0)
Metformin; Teneligliptin	0		1	(0.1)	1	(0.0)
Corticosteroids And Antiinfectives In Combination, S02ca	1	(0.1)	1	(0.1)	2	(0.1)
Acetic Acid; Dexamethasone; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Beclometasone Dipropionate; Chloramphenicol; Clotrimazole; Lidocaine Hydrochloride	1	(0.1)	0		1	(0.0)
Corticosteroids, Potent, Combinations With Antiseptics, D07bc	2	(0.1)	0		2	(0.1)
Betamethasone Valerate; Clioquinol	1	(0.1)	0		1	(0.0)
Chlorquinaldol; Diflucortolone Valerate	1	(0.1)	0		1	(0.0)
Corticosteroids, Potent, Other Combinations, D07xc	0		2	(0.1)	2	(0.1)
Betamethasone Dipropionate; Salicylic Acid	0		1	(0.1)	1	(0.0)
Mometasone Furoate; Salicylic Acid	0		1	(0.1)	1	(0.0)
Cough And Cold Preparations, R05	1	(0.1)	1	(0.1)	2	(0.1)
Cough And Cold Preparations	0		1	(0.1)	1	(0.0)
Potassium Cresolsulfonate	1	(0.1)	0		1	(0.0)
Dermatologicals, D	1	(0.1)	1	(0.1)	2	(0.1)
Dermatologicals	1	(0.1)	1	(0.1)	2	(0.1)
Direct Acting Antivirals, J05a	0		2	(0.1)	2	(0.1)
Riamilovir	0		2	(0.1)	2	(0.1)
Dopa And Dopa Derivatives, N04ba	1	(0.1)	1	(0.1)	2	(0.1)
Benserazide Hydrochloride	1	(0.1)	0		1	(0.0)
Benserazide Hydrochloride; Levodopa	0		1	(0.1)	1	(0.0)
Levodopa	1	(0.1)	0		1	(0.0)
Enzymes, B06aa	2	(0.1)	0		2	(0.1)
Bromelains; Papain; Rutoside	1	(0.1)	0		1	(0.0)
Vorhyaluronidase Alfa	1	(0.1)	0		1	(0.0)
General Nutrients, V06	1	(0.1)	1	(0.1)	2	(0.1)
General Nutrients	1	(0.1)	1	(0.1)	2	(0.1)
Glucocorticoids, R03ba	1	(0.1)	1	(0.1)	2	(0.1)
Beclometasone Dipropionate	1	(0.1)	0		1	(0.0)
Budesonide	0		1	(0.1)	1	(0.0)
Heparins Or Heparinoids For Topical Use, C05ba	0		2	(0.1)	2	(0.1)
Diethylamine Salicylate; Escin; Heparinoid	0		1	(0.1)	1	(0.0)
Heparins Or Heparinoids For Topical Use	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
High-Ceiling Diuretics And Potassium-Sparing Agents, C03eb	0		2	(0.1)	2	(0.1)
Furosemide; Spironolactone	0		1	(0.1)	1	(0.0)
Spironolactone; Torasemide	0		1	(0.1)	1	(0.0)
Iron In Combination With Folic Acid, B03ad	0		2	(0.1)	2	(0.1)
Ferrous Fumarate; Folic Acid	0		1	(0.1)	1	(0.0)
Ferrous Sulfate; Folic Acid	0		1	(0.1)	1	(0.0)
Local Anesthetics, C05ad	1	(0.1)	1	(0.1)	2	(0.1)
Lidocaine; Tribenoside	1	(0.1)	1	(0.1)	2	(0.1)
Mineral Supplements, A12	1	(0.1)	1	(0.1)	2	(0.1)
Mineral Supplements	1	(0.1)	1	(0.1)	2	(0.1)
Oral Rehydration Salt Formulations, A07ca	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Glucose; Potassium; Sodium	0		1	(0.1)	1	(0.0)
Carbohydrates Nos; Glucose; Potassium Chloride; Sodium Chloride; Sodium Citrate	1	(0.1)	0		1	(0.0)
Other Agents Against Amoebiasis And Other Protozoal Diseases, P01ax	1	(0.1)	1	(0.1)	2	(0.1)
Atovaquone	1	(0.1)	1	(0.1)	2	(0.1)
Other Anti-Dementia Drugs, N06dx	0		2	(0.1)	2	(0.1)
Memantine Hydrochloride	0		2	(0.1)	2	(0.1)
Other Antiemetics, A04ad	2	(0.1)	0		2	(0.1)
Aprepitant	2	(0.1)	0		2	(0.1)
Other Antiglaucoma Preparations, S01ex	0		2	(0.1)	2	(0.1)
Omidenepag Isopropyl	0		1	(0.1)	1	(0.0)
Ripasudil Hydrochloride Dihydrate	0		1	(0.1)	1	(0.0)
Other Antiinflammatory/Antirheumatic Agents In Combination With Other Drugs, M01bx	2	(0.1)	0		2	(0.1)
Aceclofenac; Paracetamol; Serrapeptase	2	(0.1)	0		2	(0.1)
Other Antithrombotic Agents, B01ax	2	(0.1)	0		2	(0.1)
Fondaparinux	1	(0.1)	0		1	(0.0)
Fondaparinux Sodium	1	(0.1)	0		1	(0.0)
Other Hematological Agents, B06	1	(0.1)	1	(0.1)	2	(0.1)
Haemagglutinin	1	(0.1)	1	(0.1)	2	(0.1)
Other Nervous System Drugs, N07xx	1	(0.1)	1	(0.1)	2	(0.1)
Gabapentin Enacarbil	0		1	(0.1)	1	(0.0)
Ginkgo Biloba; Nicotinic Acid; Pantothenic Acid; Pyridoxine Hydrochloride; Riboflavin; Selenium; Thioctic Acid; Vitamin B1 Nos; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Other Quaternary Ammonium Compounds, M03ac	0		2	(0.1)	2	(0.1)
Rocuronium Bromide	0		2	(0.1)	2	(0.1)
Phenothiazines With Aliphatic Side-Chain, N05aa	1	(0.1)	1	(0.1)	2	(0.1)
Chlorpromazine Hydrochloride	0		1	(0.1)	1	(0.0)
Cyamemazine	1	(0.1)	0		1	(0.0)
Pregnen (4) Derivatives, G03da	1	(0.1)	1	(0.1)	2	(0.1)
Progesterone	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Progestogens And Estrogens, Fixed Combinations, G03aa	1	(0.1)	1	(0.1)	2	(0.1)
Desogestrel; Ethinylestradiol	1	(0.1)	0		1	(0.0)
Ethinylestradiol; Norgestimate	0		1	(0.1)	1	(0.0)
Protein Supplements, V06b	2	(0.1)	0		2	(0.1)
Carbohydrates Nos; Lipids Nos; Minerals Nos; Proteins Nos	1	(0.1)	0		1	(0.0)
Soy Protein	1	(0.1)	0		1	(0.0)
Pyrimidine Derivatives, C02dc	2	(0.1)	0		2	(0.1)
Minoxidil	2	(0.1)	0		2	(0.1)
Selective Beta-2-Adrenoreceptor Agonists, R03cc	1	(0.1)	1	(0.1)	2	(0.1)
Ambroxol Hydrochloride; Clenbuterol Hydrochloride	1	(0.1)	0		1	(0.0)
Guaifenesin; Terbutaline Sulfate	0		1	(0.1)	1	(0.0)
Silicone Products, D02aa	1	(0.1)	1	(0.1)	2	(0.1)
Silicon	0		1	(0.1)	1	(0.0)
Silicone Products	1	(0.1)	0		1	(0.0)
Soft Paraffin And Fat Products, D02ac	1	(0.1)	1	(0.1)	2	(0.1)
Petrolatum	1	(0.1)	0		1	(0.0)
White Soft Paraffin	0		1	(0.1)	1	(0.0)
Specific Immunoglobulins, J06bb	0		2	(0.1)	2	(0.1)
Immunoglobulin Equine Anti-Rabies	0		1	(0.1)	1	(0.0)
Immunoglobulin Human Anti-Tetanus	0		1	(0.1)	1	(0.0)
Sympathomimetics In Glaucoma Therapy, S01ea	1	(0.1)	1	(0.1)	2	(0.1)
Apraclonidine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Sympathomimetics Used As Decongestants, S01ga	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine Maleate; Chondroitin Sulfate Sodium; Neostigmine Metilsulfate; Potassium Aspartate; Pyridoxine Hydrochloride; Retinol Palmitate; Taurine; Tetryzoline Hydrochloride; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dipotassium Glycyrrhizate; Pyridoxine Hydrochloride; Tetryzoline Hydrochloride	0		1	(0.1)	1	(0.0)
Chlorphenamine Maleate; Tetryzoline Hydrochloride	0		1	(0.1)	1	(0.0)
Sympathomimetics, Combinations Excl. Corticosteroids, R01ab	2	(0.1)	0		2	(0.1)
Acetylcysteine; Tuaminoheptane Sulfate	2	(0.1)	0		2	(0.1)
Sympathomimetics, Plain, R01aa	1	(0.1)	1	(0.1)	2	(0.1)
Oxymetazoline Hydrochloride	1	(0.1)	0		1	(0.0)
Tuaminoheptane	0		1	(0.1)	1	(0.0)
Topoisomerase 1 (Top1) Inhibitors, L01ce	2	(0.1)	0		2	(0.1)
Irinotecan	1	(0.1)	0		1	(0.0)
Topotecan Hydrochloride	1	(0.1)	0		1	(0.0)
Urinary Concrement Solvents, G04bc	0		2	(0.1)	2	(0.1)
Anethole; Borneol; Camphene; Cineole; Fenchone; Pinene	0		1	(0.1)	1	(0.0)
Magnesium Citrate; Potassium Citrate; Pyridoxine Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Zinc, A12cb	1	(0.1)	1	(0.1)	2	(0.1)
Zinc	0		1	(0.1)	1	(0.0)
Zinc Citrate	1	(0.1)	0		1	(0.0)
All Other Therapeutic Products, V03a	0		1	(0.1)	1	(0.0)
Meglumine Sodium Succinate	0		1	(0.1)	1	(0.0)
Amino Acids And Derivatives, A16aa	1	(0.1)	0		1	(0.0)
Levocarnitine Hydrochloride; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Amino Acids, Incl. Combinations With Polypeptides, V06dd	1	(0.1)	0		1	(0.0)
Aspartic Acid	1	(0.1)	0		1	(0.0)
Analgesics, N02	0		1	(0.1)	1	(0.0)
Analgesics	0		1	(0.1)	1	(0.0)
Anesthetics For Topical Use, D04ab	0		1	(0.1)	1	(0.0)
Lidocaine	0		1	(0.1)	1	(0.0)
Anesthetics, General, N01a	0		1	(0.1)	1	(0.0)
Anesthetics, General	0		1	(0.1)	1	(0.0)
Antacids, Other Combinations, A02ax	1	(0.1)	0		1	(0.0)
Aluminium Silicate; Calcium Carbonate; Cinnamomum Spp. Bark; Citrus Deliciosa Peel; Diastase; Foeniculum Vulgare; Gentiana Lutea Root; Magnesium Carbonate; Myristica Fragrans; Picrasma Quassioides Wood; Sodium	1	(0.1)	0		1	(0.0)
Anti-Androgens, L02bb	1	(0.1)	0		1	(0.0)
Bicalutamide	1	(0.1)	0		1	(0.0)
Antiarrhythmics, Class Ib, C01bb02	0		1	(0.1)	1	(0.0)
Mexiletine	0		1	(0.1)	1	(0.0)
Antibacterials For Systemic Use, J01	1	(0.1)	0		1	(0.0)
D-Mannose; Lactobacillus Acidophilus	1	(0.1)	0		1	(0.0)
Antibiotics, J04ab	1	(0.1)	0		1	(0.0)
Rifapentine	1	(0.1)	0		1	(0.0)
Antivirals For Treatment Of Hcv Infections, J05ap	0		1	(0.1)	1	(0.0)
Sofosbuvir; Velpatasvir	0		1	(0.1)	1	(0.0)
Antivirals, D06bb	1	(0.1)	0		1	(0.0)
Docosanol	1	(0.1)	0		1	(0.0)
Ascorbic Acid (Vitamin C), Plain, A11ga	0		1	(0.1)	1	(0.0)
Ascorbic Acid	0		1	(0.1)	1	(0.0)
Barbiturates And Derivatives, N03aa	0		1	(0.1)	1	(0.0)
Primidone	0		1	(0.1)	1	(0.0)
Bcr-Abl Tyrosine Kinase Inhibitors, L01ea	1	(0.1)	0		1	(0.0)
Dasatinib Monohydrate	1	(0.1)	0		1	(0.0)
Benzamides, N05al	0		1	(0.1)	1	(0.0)
Amisulpride	0		1	(0.1)	1	(0.0)
Benzomorphan Derivatives, N02ad	0		1	(0.1)	1	(0.0)
Pentazocine	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Beta Blocking Agents, Selective, And Thiazides, C07bb	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Metoprolol Succinate	1	(0.1)	0		1	(0.0)
Bile And Liver Therapy, A05	1	(0.1)	0		1	(0.0)
Bicyclol	1	(0.1)	0		1	(0.0)
Bisphosphonates, Combinations, M05bb	1	(0.1)	0		1	(0.0)
Alendronate Sodium; Colecalciferol	1	(0.1)	0		1	(0.0)
Butyrophenone Derivatives, N05ad	1	(0.1)	0		1	(0.0)
Haloperidol	1	(0.1)	0		1	(0.0)
Calcineurin Inhibitors, L04ad	1	(0.1)	0		1	(0.0)
Ciclosporin	1	(0.1)	0		1	(0.0)
Carbohydrates/Proteins/Minerals/Vitamins, Combinations, V06da	0		1	(0.1)	1	(0.0)
Carbohydrates Nos; Minerals Nos; Proteins Nos; Vitamins Nos	0		1	(0.1)	1	(0.0)
Carboxamide Derivatives, N03af01	0		1	(0.1)	1	(0.0)
Carbamazepine	0		1	(0.1)	1	(0.0)
Caries Prophylactic Agents, A01aa	0		1	(0.1)	1	(0.0)
Calcium Chloride Dihydrate; Magnesium Chloride; Potassium Chloride; Potassium Phosphate Dibasic; Sodium Chloride	0		1	(0.1)	1	(0.0)
Centrally Acting Antiobesity Products, A08aa	1	(0.1)	0		1	(0.0)
Bupropion Hydrochloride; Naltrexone Hydrochloride	1	(0.1)	0		1	(0.0)
Choline Derivatives, M03ab	0		1	(0.1)	1	(0.0)
Suxamethonium Chloride	0		1	(0.1)	1	(0.0)
Choline Esters, N07ab	1	(0.1)	0		1	(0.0)
Bethanechol Chloride	1	(0.1)	0		1	(0.0)
Combinations Of Antineoplastic Agents, L01xy	1	(0.1)	0		1	(0.0)
Fluorouracil; Folinic Acid; Oxaliplatin	1	(0.1)	0		1	(0.0)
Corticosteroids And Antiinfectives In Combination, S03ca	0		1	(0.1)	1	(0.0)
Dexamethasone Sodium Phosphate; Netilmicin Sulfate	0		1	(0.1)	1	(0.0)
Corticosteroids, Plain, D07a	1	(0.1)	0		1	(0.0)
Deprodone Propionate	1	(0.1)	0		1	(0.0)
Corticosteroids, Plain, S01ba	0		1	(0.1)	1	(0.0)
Loteprednol Etabonate	0		1	(0.1)	1	(0.0)
Corticosteroids, Very Potent, Other Combinations, D07xd	0		1	(0.1)	1	(0.0)
Clobetasol Propionate; Salicylic Acid	0		1	(0.1)	1	(0.0)
Cosmetics, V07at	0		1	(0.1)	1	(0.0)
Cosmetics	0		1	(0.1)	1	(0.0)
Cyclic Amines, J05ac	1	(0.1)	0		1	(0.0)
Rimantadine Hydrochloride	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Emollients And Protectives, D02	1	(0.1)	0		1	(0.0)
Avena Sativa; Beta Glucan; Linum Usitatissimum; Tocopherol; Xylitol	1	(0.1)	0		1	(0.0)
Enemas, A06ag	0		1	(0.1)	1	(0.0)
Glycerol; Polysorbate 80; Sodium Citrate; Sorbitol	0		1	(0.1)	1	(0.0)
Enzymes, M09ab	1	(0.1)	0		1	(0.0)
Amylase; Bromelains; Chymotrypsin; Lipase; Pancreatin; Papain; Rutoside; Trypsin	1	(0.1)	0		1	(0.0)
Ergot Alkaloids, C04ae	0		1	(0.1)	1	(0.0)
Nicergoline	0		1	(0.1)	1	(0.0)
Ergot Alkaloids, N02ca	1	(0.1)	0		1	(0.0)
Caffeine; Cyclizine Hydrochloride; Ergotamine Tartrate	1	(0.1)	0		1	(0.0)
Expectorants, Excl. Combinations With Cough Suppressants, R05c	0		1	(0.1)	1	(0.0)
Ambroxol; Guaifenesin; Levosalbutamol	0		1	(0.1)	1	(0.0)
Fluoroquinolones, S01ae	1	(0.1)	0		1	(0.0)
Besifloxacin Hydrochloride	1	(0.1)	0		1	(0.0)
Gonadotropin Releasing Hormone Analogues, L02ae	1	(0.1)	0		1	(0.0)
Goserelin Acetate	1	(0.1)	0		1	(0.0)
Hydrazides, J04ac	1	(0.1)	0		1	(0.0)
Isoniazid	1	(0.1)	0		1	(0.0)
Imidazole Derivatives, J01xd	1	(0.1)	0		1	(0.0)
Cow Bezoar; Metronidazole	1	(0.1)	0		1	(0.0)
Interferons, L03ab	0		1	(0.1)	1	(0.0)
Interferon Alfa-2b	0		1	(0.1)	1	(0.0)
Iodine (125i) Compounds, V09gb	1	(0.1)	0		1	(0.0)
Iodinated (125 I) Human Serum Albumin	1	(0.1)	0		1	(0.0)
Iron Trivalent, Oral Preparations, B03ab	1	(0.1)	0		1	(0.0)
Ferric Hydroxide Polymaltose Complex	1	(0.1)	0		1	(0.0)
Lipid Modifying Agents In Combination With Other Drugs, C10bx	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Atorvastatin L-Lysine	1	(0.1)	0		1	(0.0)
Low-Ceiling Diuretics And Potassium-Sparing Agents, C03ea	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Spironolactone	1	(0.1)	0		1	(0.0)
Medicated Dressings With Antiinfectives, D09aa	0		1	(0.1)	1	(0.0)
Leptospermum Scoparium; Manuka Honey	0		1	(0.1)	1	(0.0)
Nasal Preparations, R01	1	(0.1)	0		1	(0.0)
Nasal Preparations	1	(0.1)	0		1	(0.0)
Nicotinic Acid And Derivatives, C10ad	1	(0.1)	0		1	(0.0)
Nicotinic Acid	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors, J05af	1	(0.1)	0		1	(0.0)
Emtricitabine	1	(0.1)	0		1	(0.0)
Tenofovir Disoproxil	1	(0.1)	0		1	(0.0)
Other Antiallergics, S01gx	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Chondroitin Sulfate Sodium; Cromoglicate Sodium; Dipotassium Glycyrrhizate	1	(0.1)	0		1	(0.0)
Other Antiarrhythmics, Class I And Iii, C01bg	1	(0.1)	0		1	(0.0)
Cibenzoline Succinate	1	(0.1)	0		1	(0.0)
Other Antidiarrheals, A07x	1	(0.1)	0		1	(0.0)
Other Antidiarrheals	1	(0.1)	0		1	(0.0)
Other Antimigraine Preparations, N02cx	0		1	(0.1)	1	(0.0)
Lomerizine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antineoplastic Agents, L01xx	0		1	(0.1)	1	(0.0)
Ivosidenib	0		1	(0.1)	1	(0.0)
Other Antipruritics, D04ax	1	(0.1)	0		1	(0.0)
Calamine; Light Liquid Paraffin	1	(0.1)	0		1	(0.0)
Other Antiseptics And Disinfectants, D08ax	1	(0.1)	0		1	(0.0)
Ethanol; Methylrosanilinium Chloride	1	(0.1)	0		1	(0.0)
Other Antispasmodics In Combination With Analgesics, A03dc	0		1	(0.1)	1	(0.0)
Metamizole Sodium; Pitofenone Hydrochloride	0		1	(0.1)	1	(0.0)
Other Beta-Lactam Antibacterials, J01d	0		1	(0.1)	1	(0.0)
Cephalosporin Nos	0		1	(0.1)	1	(0.0)
Other Blood Products, B05ax	1	(0.1)	0		1	(0.0)
Red Blood Cells	1	(0.1)	0		1	(0.0)
Other Cephalosporins And Penems, J01di	1	(0.1)	0		1	(0.0)
Faropenem Sodium	1	(0.1)	0		1	(0.0)
Other Combinations Of Nutrients, V06dx	0		1	(0.1)	1	(0.0)
Creatine	0		1	(0.1)	1	(0.0)
Other Dermatologicals, D11ax	0		1	(0.1)	1	(0.0)
Spermidine	0		1	(0.1)	1	(0.0)
Other Diagnostic Agents, V04cx	1	(0.1)	0		1	(0.0)
Urea 13 C	1	(0.1)	0		1	(0.0)
Other Drugs Used In Benign Prostatic Hypertrophy, G04cx	1	(0.1)	0		1	(0.0)
Copper Gluconate; Lycopene; Serenoa Repens; Sitosterol; Zinc Sulfate Monohydrate	1	(0.1)	0		1	(0.0)
Other Drugs Used In Diabetes, A10x	0		1	(0.1)	1	(0.0)
Riboflavin; Rutoside; Thioctic Acid; Vitamin B1 Nos	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Mineral Products, A12cx	0		1	(0.1)	1	(0.0)
Boron; Calcium Citrate Malate; Copper Sulfate; Magnesium Hydroxide; Manganese Sulfate; Sodium Borate; Zinc Sulfate	0		1	(0.1)	1	(0.0)
Other Mineral Supplements, A12c	1	(0.1)	0		1	(0.0)
Magnesium; Sodium Chloride	1	(0.1)	0		1	(0.0)
Other Plain Vitamin Preparations, A11ha	1	(0.1)	0		1	(0.0)
Biotin	1	(0.1)	0		1	(0.0)
Other Potassium-Sparing Agents, C03db	1	(0.1)	0		1	(0.0)
Amiloride	1	(0.1)	0		1	(0.0)
Other Respiratory System Products, R07ax	0		1	(0.1)	1	(0.0)
Anemarrhena Asphodeloides Rhizome; Calcium Sulfate; Cimicifuga Spp. Rhizome; Eriobotrya Japonica Leaf; Gardenia Jasminoides Fruit; Lilium Spp. Bulb; Magnolia Spp. Flower; Ophiopogon Japonicus Tuber; Scutellar	0		1	(0.1)	1	(0.0)
Other Surgical Aids, S01kx	0		1	(0.1)	1	(0.0)
Calcium Chloride Dihydrate; Glucose; Magnesium Sulfate; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Other Systemic Drugs For Obstructive Airway Diseases, R03dx	0		1	(0.1)	1	(0.0)
Suplatast Tosilate	0		1	(0.1)	1	(0.0)
Other Therapeutic Products, V03ax	1	(0.1)	0		1	(0.0)
Homeopathics Nos	1	(0.1)	0		1	(0.0)
Other Topical Products For Joint And Muscular Pain, M02ax	0		1	(0.1)	1	(0.0)
Other Topical Products For Joint And Muscular Pain	0		1	(0.1)	1	(0.0)
Otologicals, S02	1	(0.1)	0		1	(0.0)
Otologicals	1	(0.1)	0		1	(0.0)
Paramagnetic Contrast Media, V08ca	0		1	(0.1)	1	(0.0)
Gadoteric Acid	0		1	(0.1)	1	(0.0)
Phosphodiesterase Inhibitors, C01ce	0		1	(0.1)	1	(0.0)
Milrinone	0		1	(0.1)	1	(0.0)
Polymyxins, J01xb	1	(0.1)	0		1	(0.0)
Polymyxin	1	(0.1)	0		1	(0.0)
Progesterone Receptor Modulators, G03xb	1	(0.1)	0		1	(0.0)
Mifepristone	1	(0.1)	0		1	(0.0)
Protease Inhibitors, J05ae	0		1	(0.1)	1	(0.0)
Protease Inhibitors	0		1	(0.1)	1	(0.0)
Softeners, Emollients, A06aa	0		1	(0.1)	1	(0.0)
Magnesium Hydroxide; Paraffin, Liquid; Sodium Picosulfate	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Solvents And Diluting Agents, Incl. Irrigating Solutions, V07ab	0		1	(0.1)	1	(0.0)
Water For Injection	0		1	(0.1)	1	(0.0)
Synthetic Anticholinergic Agents In Combination With Psycholeptics, A03ca	1	(0.1)	0		1	(0.0)
Chlordiazepoxide; Clidinium Bromide; Dicycloverine Hydrochloride	1	(0.1)	0		1	(0.0)
Taxanes, L01cd	0		1	(0.1)	1	(0.0)
Paclitaxel Albumin	0		1	(0.1)	1	(0.0)
Thiouracils, H03ba	1	(0.1)	0		1	(0.0)
Propylthiouracil	1	(0.1)	0		1	(0.0)
Tumor Necrosis Factor Alpha (Tnf-) Inhibitors, L04ab	0		1	(0.1)	1	(0.0)
Adalimumab	0		1	(0.1)	1	(0.0)
Various, V	1	(0.1)	0		1	(0.0)
Radiotherapy	1	(0.1)	0		1	(0.0)
Vasopressin Antagonists, C03xa	1	(0.1)	0		1	(0.0)
Tolvaptan	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Incl. Combinations, A11e	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Incl. Combinations	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Other Combinations, A11ex	0		1	(0.1)	1	(0.0)
Bacillus Coagulans; Dexpanthenol; Folic Acid; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Vitamin K, B02ba	0		1	(0.1)	1	(0.0)
Vitamin K Nos	0		1	(0.1)	1	(0.0)
Watersoluble, Nephrotropic, High Osmolar X-Ray Contrast Media, V08aa	0		1	(0.1)	1	(0.0)
Meglumine Amidotrizoate; Sodium Amidotrizoate	0		1	(0.1)	1	(0.0)
Zinc Products, D02ab	1	(0.1)	0		1	(0.0)
Benzyl Alcohol; Benzyl Benzoate; Benzyl Cinnamate; Wool Fat; Zinc Oxide	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.1.27 Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	1880		1878		3758	
All medications	1618	(86.1)	1635	(87.1)	3253	(86.6)
Insulins And Analogues For Injection, Long-Acting, A10ae	847	(45.0)	896	(47.7)	1743	(46.4)
Insulin Glargine	433	(23.0)	433	(23.1)	866	(23.0)
Insulin Degludec	384	(20.4)	434	(23.1)	818	(21.8)
Insulin Detemir	22	(1.2)	11	(0.6)	33	(0.9)
Insulin Glargine Biosimilar 1	10	(0.5)	19	(1.0)	29	(0.8)
Insulin Degludec; Liraglutide	1	(0.1)	8	(0.4)	9	(0.2)
Insulin Glargine; Lixisenatide	2	(0.1)	0		2	(0.1)
Other Viral Vaccines, J07bx	666	(35.4)	683	(36.4)	1349	(35.9)
Tozinameran	464	(24.7)	458	(24.4)	922	(24.5)
Elasomeran	134	(7.1)	130	(6.9)	264	(7.0)
Covid-19 Vaccine Nrvv Ad (Chadox1 Ncov-19)	59	(3.1)	61	(3.2)	120	(3.2)
Covid-19 Vaccine	39	(2.1)	39	(2.1)	78	(2.1)
Covid-19 Vaccine Nrvv Ad26 (Gam-Covid-Vac)	24	(1.3)	31	(1.6)	55	(1.5)
Covid-19 Vaccine Inact (Vero)	15	(0.8)	9	(0.5)	24	(0.6)
Covid-19 Vaccine Inact (Vero) Hb02	2	(0.1)	14	(0.8)	16	(0.4)
Covid-19 Vaccine Inact (Vero) Cz02	5	(0.3)	4	(0.2)	9	(0.2)
Covid-19 Vaccine Nrvv Ad26 (Jnj 78436735)	3	(0.2)	3	(0.2)	6	(0.2)
Covid-19 Vaccine Nrvv Ad5 (Gam-Covid-Vac)	1	(0.1)	0		1	(0.0)
Covid-19 Vaccine Prot. Subunit (Epivaccorona)	1	(0.1)	0		1	(0.0)
Mvc-Cov1901	0		1	(0.1)	1	(0.0)
Multiple Atc, 0	505	(26.9)	524	(27.9)	1029	(27.4)
Azithromycin	50	(2.7)	43	(2.3)	93	(2.5)
Levofloxacin	30	(1.6)	33	(1.8)	63	(1.7)
Lidocaine	31	(1.6)	27	(1.4)	58	(1.5)
Prednisone	24	(1.3)	27	(1.4)	51	(1.4)
Ciprofloxacin	30	(1.6)	20	(1.1)	50	(1.3)
Dexamethasone	26	(1.4)	20	(1.1)	46	(1.2)
Sodium Chloride	22	(1.2)	20	(1.1)	42	(1.1)
Ascorbic Acid	20	(1.1)	21	(1.1)	41	(1.1)
Acetylcysteine	18	(1.0)	16	(0.8)	34	(0.9)
Hyaluronate Sodium	14	(0.7)	17	(0.9)	31	(0.8)
Mecobalamin	14	(0.7)	14	(0.8)	28	(0.8)
Methylprednisolone	13	(0.7)	14	(0.8)	27	(0.7)
Metronidazole	12	(0.6)	15	(0.8)	27	(0.7)
Nimesulide	12	(0.6)	15	(0.8)	27	(0.7)
Fluconazole	8	(0.4)	16	(0.8)	24	(0.6)
Chlorphenamine Maleate	7	(0.4)	16	(0.8)	23	(0.6)
Triamcinolone Acetonide	8	(0.4)	14	(0.8)	22	(0.6)
Clarithromycin	9	(0.5)	11	(0.6)	20	(0.5)
Clindamycin	9	(0.5)	11	(0.6)	20	(0.5)
Budesonide	10	(0.5)	8	(0.4)	18	(0.5)
Cefuroxime	11	(0.6)	7	(0.4)	18	(0.5)
Ciprofloxacin Hydrochloride	6	(0.3)	12	(0.6)	18	(0.5)
Clotrimazole	11	(0.6)	7	(0.4)	18	(0.5)
Ofloxacin	8	(0.4)	9	(0.5)	17	(0.5)
Prednisolone	8	(0.4)	9	(0.5)	17	(0.5)
Ambroxol Hydrochloride	7	(0.4)	9	(0.5)	16	(0.4)
Caffeine	6	(0.3)	10	(0.5)	16	(0.4)
Mometasone Furoate	7	(0.4)	9	(0.5)	16	(0.4)
Moxifloxacin Hydrochloride	4	(0.2)	12	(0.6)	16	(0.4)
Metoclopramide	6	(0.3)	8	(0.4)	14	(0.4)
Ambroxol	7	(0.4)	6	(0.3)	13	(0.3)
Betamethasone	8	(0.4)	5	(0.3)	13	(0.3)
Fluorometholone	5	(0.3)	8	(0.4)	13	(0.3)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Gentamicin Sulfate	6	(0.3)	7	(0.4)	13	(0.3)
Hydrocortisone	9	(0.5)	4	(0.2)	13	(0.3)
Morphine	4	(0.2)	8	(0.4)	12	(0.3)
Vancomycin	6	(0.3)	6	(0.3)	12	(0.3)
Aciclovir	4	(0.2)	7	(0.4)	11	(0.3)
Clobetasol Propionate	3	(0.2)	8	(0.4)	11	(0.3)
Iron	5	(0.3)	6	(0.3)	11	(0.3)
Ketoconazole	7	(0.4)	4	(0.2)	11	(0.3)
Lidocaine Hydrochloride	4	(0.2)	7	(0.4)	11	(0.3)
Multivitamins, Plain	8	(0.4)	3	(0.2)	11	(0.3)
Acetazolamide	4	(0.2)	6	(0.3)	10	(0.3)
Benzydamine Hydrochloride	6	(0.3)	4	(0.2)	10	(0.3)
Chlorhexidine Gluconate	6	(0.3)	4	(0.2)	10	(0.3)
Cortisone	4	(0.2)	6	(0.3)	10	(0.3)
Fluticasone	3	(0.2)	7	(0.4)	10	(0.3)
Glycyrrhiza Spp. Root; Paeonia Lactiflora Root	4	(0.2)	6	(0.3)	10	(0.3)
Meclozine	3	(0.2)	7	(0.4)	10	(0.3)
Betamethasone Sodium Phosphate	2	(0.1)	7	(0.4)	9	(0.2)
Betamethasone Valerate; Gentamicin Sulfate	3	(0.2)	6	(0.3)	9	(0.2)
Chlorphenamine	4	(0.2)	5	(0.3)	9	(0.2)
Dimeticone	4	(0.2)	5	(0.3)	9	(0.2)
Fluticasone Furoate	4	(0.2)	5	(0.3)	9	(0.2)
Heparinoid	6	(0.3)	3	(0.2)	9	(0.2)
Moxifloxacin	5	(0.3)	4	(0.2)	9	(0.2)
Pyridoxine	3	(0.2)	6	(0.3)	9	(0.2)
Sodium Bicarbonate	3	(0.2)	6	(0.3)	9	(0.2)
Terbinafine Hydrochloride	3	(0.2)	6	(0.3)	9	(0.2)
All Other Therapeutic Products	3	(0.2)	5	(0.3)	8	(0.2)
Betamethasone Valerate	3	(0.2)	5	(0.3)	8	(0.2)
Bupivacaine	2	(0.1)	6	(0.3)	8	(0.2)
Dexamethasone Sodium Phosphate	3	(0.2)	5	(0.3)	8	(0.2)
Docusate Sodium	1	(0.1)	7	(0.4)	8	(0.2)
Pyridoxine Hydrochloride	4	(0.2)	4	(0.2)	8	(0.2)
Sulfamethoxazole	4	(0.2)	4	(0.2)	8	(0.2)
Zinc	5	(0.3)	3	(0.2)	8	(0.2)
Magnesium Sulfate	2	(0.1)	5	(0.3)	7	(0.2)
Xylometazoline Hydrochloride	2	(0.1)	5	(0.3)	7	(0.2)
Bepotastine Besilate	3	(0.2)	3	(0.2)	6	(0.2)
Betamethasone Butyrate Propionate	1	(0.1)	5	(0.3)	6	(0.2)
Brimonidine Tartrate	3	(0.2)	3	(0.2)	6	(0.2)
Cefuroxime Sodium	2	(0.1)	4	(0.2)	6	(0.2)
Dequalinium Chloride	4	(0.2)	2	(0.1)	6	(0.2)
Difluprednate	3	(0.2)	3	(0.2)	6	(0.2)
Hydrocortisone Butyrate	2	(0.1)	4	(0.2)	6	(0.2)
Interferon Alfa-2b	5	(0.3)	1	(0.1)	6	(0.2)
Lactobacillus Acidophilus	4	(0.2)	2	(0.1)	6	(0.2)
Menthol	2	(0.1)	4	(0.2)	6	(0.2)
Methylprednisolone Acetate	1	(0.1)	5	(0.3)	6	(0.2)
Metoclopramide Hydrochloride	2	(0.1)	4	(0.2)	6	(0.2)
Oxybuprocaine Hydrochloride	2	(0.1)	4	(0.2)	6	(0.2)
Oxymetazoline Hydrochloride	3	(0.2)	3	(0.2)	6	(0.2)
Pronase	2	(0.1)	4	(0.2)	6	(0.2)
Rifaximin	2	(0.1)	4	(0.2)	6	(0.2)
Tolperisone	4	(0.2)	2	(0.1)	6	(0.2)
Triamcinolone	3	(0.2)	3	(0.2)	6	(0.2)
Betamethasone Dipropionate; Betamethasone Sodium Phosphate	3	(0.2)	2	(0.1)	5	(0.1)
Calcium Sulfate Dihydrate; Dryopteris Crassirhizoma Rhizome; Ephedra Spp. Herb; Forsythia Suspensa; Glycyrrhiza Spp. Root With Rhizome; Houttuynia Cordata Herb; Isatis Tinctoria Root; Lonicera Japonica Flowe	0		5	(0.3)	5	(0.1)
Clindamycin Phosphate	0		5	(0.3)	5	(0.1)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dexpanthenol	2	(0.1)	3	(0.2)	5	(0.1)
Erythromycin	2	(0.1)	3	(0.2)	5	(0.1)
Formoterol	2	(0.1)	3	(0.2)	5	(0.1)
Guaiazulene	2	(0.1)	3	(0.2)	5	(0.1)
Ivermectin	1	(0.1)	4	(0.2)	5	(0.1)
Macrogol	1	(0.1)	4	(0.2)	5	(0.1)
Methylethylpiridinol Succinate	2	(0.1)	3	(0.2)	5	(0.1)
Pilocarpine Hydrochloride	4	(0.2)	1	(0.1)	5	(0.1)
Povidone-Iodine	2	(0.1)	3	(0.2)	5	(0.1)
Propylene Glycol	4	(0.2)	1	(0.1)	5	(0.1)
Saccharated Iron Oxide	3	(0.2)	2	(0.1)	5	(0.1)
Salmeterol	2	(0.1)	3	(0.2)	5	(0.1)
Sodium Gualenate Hydrate	1	(0.1)	4	(0.2)	5	(0.1)
Sucralfate	3	(0.2)	2	(0.1)	5	(0.1)
Terbinafine	3	(0.2)	2	(0.1)	5	(0.1)
Vitamin B12 Nos	4	(0.2)	1	(0.1)	5	(0.1)
Ademetionine	1	(0.1)	3	(0.2)	4	(0.1)
Amikacin Sulfate	2	(0.1)	2	(0.1)	4	(0.1)
Atropine Sulfate	1	(0.1)	3	(0.2)	4	(0.1)
Azelastine Hydrochloride	1	(0.1)	3	(0.2)	4	(0.1)
Cannabidiol	1	(0.1)	3	(0.2)	4	(0.1)
Dimenhydrinate	2	(0.1)	2	(0.1)	4	(0.1)
Fluocinonide	4	(0.2)	0		4	(0.1)
Gentamicin	1	(0.1)	3	(0.2)	4	(0.1)
Lactobacillus Nos	1	(0.1)	3	(0.2)	4	(0.1)
Magnesium Aspartate; Potassium Aspartate	1	(0.1)	3	(0.2)	4	(0.1)
Miconazole	1	(0.1)	3	(0.2)	4	(0.1)
Minerals Nos; Vitamins Nos	3	(0.2)	1	(0.1)	4	(0.1)
Mupirocin	2	(0.1)	2	(0.1)	4	(0.1)
Neomycin	2	(0.1)	2	(0.1)	4	(0.1)
Nystatin	1	(0.1)	3	(0.2)	4	(0.1)
Oxygen	2	(0.1)	2	(0.1)	4	(0.1)
Potassium Aspartate	1	(0.1)	3	(0.2)	4	(0.1)
Prochlorperazine	3	(0.2)	1	(0.1)	4	(0.1)
Sildenafil Citrate	3	(0.2)	1	(0.1)	4	(0.1)
Sulfadiazine Silver	0		4	(0.2)	4	(0.1)
Vitamins Nos	2	(0.1)	2	(0.1)	4	(0.1)
Xylometazoline	0		4	(0.2)	4	(0.1)
Zinc Oxide	1	(0.1)	3	(0.2)	4	(0.1)
Aconitum Spp. Processed Root; Asarum Spp. Root; Ephedra Spp. Herb	2	(0.1)	1	(0.1)	3	(0.1)
Alisma Orientale Tuber; Atractylodes Lancea Rhizome; Cinnamomum Cassia Bark; Polyporus Umbellatus Sclerotium; Poria Cocos Sclerotium	0		3	(0.2)	3	(0.1)
Ampicillin	0		3	(0.2)	3	(0.1)
Antibiotics	1	(0.1)	2	(0.1)	3	(0.1)
Asarum Spp. Root; Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Pinellia Ternata Tuber; Schisandra Chinensis Fruit; Zingiber Officinale Rhizome	2	(0.1)	1	(0.1)	3	(0.1)
Ascorbic Acid; Ferrous Sulfate	1	(0.1)	2	(0.1)	3	(0.1)
Benzydamine	0		3	(0.2)	3	(0.1)
Betamethasone Dipropionate	2	(0.1)	1	(0.1)	3	(0.1)
Bupivacaine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Calcifediol	1	(0.1)	2	(0.1)	3	(0.1)
Charcoal, Activated	0		3	(0.2)	3	(0.1)
Ciclesonide	2	(0.1)	1	(0.1)	3	(0.1)
Cinnamomum Cassia Bark; Ephedra Spp. Herb; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Pueraria Lobata Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	1	(0.1)	2	(0.1)	3	(0.1)
Colistin; Erythromycin Lactobionate	1	(0.1)	2	(0.1)	3	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Cromoglicate Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Desonide	3	(0.2)	0		3	(0.1)
Dimetindene Maleate	0		3	(0.2)	3	(0.1)
Fluorescein Sodium	1	(0.1)	2	(0.1)	3	(0.1)
Fusidic Acid	2	(0.1)	1	(0.1)	3	(0.1)
Gatifloxacin	0		3	(0.2)	3	(0.1)
Levofloxacin Hemihydrate	1	(0.1)	2	(0.1)	3	(0.1)
Levomenthol	1	(0.1)	2	(0.1)	3	(0.1)
Meldonium	1	(0.1)	2	(0.1)	3	(0.1)
Methyl Salicylate	1	(0.1)	2	(0.1)	3	(0.1)
Miconazole Nitrate	3	(0.2)	0		3	(0.1)
Miramistin	1	(0.1)	2	(0.1)	3	(0.1)
Mometasone	2	(0.1)	1	(0.1)	3	(0.1)
Naloxone Hydrochloride; Oxycodone Hydrochloride	3	(0.2)	0		3	(0.1)
Naloxone Hydrochloride; Tilidine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Norfloxacin	1	(0.1)	2	(0.1)	3	(0.1)
Ofloxacin; Ornidazole	2	(0.1)	1	(0.1)	3	(0.1)
Ornidazole	2	(0.1)	1	(0.1)	3	(0.1)
Oxiglutatione	0		3	(0.2)	3	(0.1)
Pheniramine Maleate	1	(0.1)	2	(0.1)	3	(0.1)
Phenol	2	(0.1)	1	(0.1)	3	(0.1)
Plantago Ovata	1	(0.1)	2	(0.1)	3	(0.1)
Promethazine	2	(0.1)	1	(0.1)	3	(0.1)
Sildenafil	3	(0.2)	0		3	(0.1)
Sodium Alginate	1	(0.1)	2	(0.1)	3	(0.1)
Sodium Citrate Acid	0		3	(0.2)	3	(0.1)
Tacrolimus	2	(0.1)	1	(0.1)	3	(0.1)
Terbutaline Sulfate	1	(0.1)	2	(0.1)	3	(0.1)
Tolperisone Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Urea	0		3	(0.2)	3	(0.1)
Albumin Human	0		2	(0.1)	2	(0.1)
Alclometasone Dipropionate	1	(0.1)	1	(0.1)	2	(0.1)
Amantadine	2	(0.1)	0		2	(0.1)
Ammonium Chloride	2	(0.1)	0		2	(0.1)
Anesthetics, Local	1	(0.1)	1	(0.1)	2	(0.1)
Angelica Sinensis; Ligusticum Chuanxiong	0		2	(0.1)	2	(0.1)
Arctium Lappa Fruit; Cicada Slough; Ephedra Spp. Herb; Eriobotrya Japonica Leaf; Perilla Frutescens Fruit; Perilla Frutescens Leaf; Peucedanum Praeruptorum Root; Pheretima Spp.; Schisandra Chinensis Fruit	1	(0.1)	1	(0.1)	2	(0.1)
Arnica Montana	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Zinc	0		2	(0.1)	2	(0.1)
Azelastine	1	(0.1)	1	(0.1)	2	(0.1)
Azithromycin Dihydrate	2	(0.1)	0		2	(0.1)
Bacitracin; Neomycin; Polymyxin B	1	(0.1)	1	(0.1)	2	(0.1)
Baicalin; Buffalo Horn; Cholic Acid; Concha Margaritifera; Gardenia Jasminoides Fruit; Hyodeoxycholic Acid; Isatis Tinctoria Root; Lonicera Japonica Flower	0		2	(0.1)	2	(0.1)
Beclometasone Dipropionate	1	(0.1)	1	(0.1)	2	(0.1)
Benzethonium Chloride	1	(0.1)	1	(0.1)	2	(0.1)
Benzocaine	2	(0.1)	0		2	(0.1)
Benzodiazepine Derivatives	0		2	(0.1)	2	(0.1)
Berberine	0		2	(0.1)	2	(0.1)
Betamethasone Acetate; Betamethasone Sodium Phosphate	1	(0.1)	1	(0.1)	2	(0.1)
Betamethasone Dipropionate; Gentamicin Sulfate	1	(0.1)	1	(0.1)	2	(0.1)
Blood, Calf, Deprot., Lmw Portion	1	(0.1)	1	(0.1)	2	(0.1)
Buprenorphine	2	(0.1)	0		2	(0.1)
Buprenorphine Hydrochloride	2	(0.1)	0		2	(0.1)
Calcium Phosphate	2	(0.1)	0		2	(0.1)
Camphor; Menthol; Methyl Salicylate	2	(0.1)	0		2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Carmellose	0		2	(0.1)	2	(0.1)
Carmellose Sodium	0		2	(0.1)	2	(0.1)
Casirivimab	1	(0.1)	1	(0.1)	2	(0.1)
Casirivimab; Imdevimab	1	(0.1)	1	(0.1)	2	(0.1)
Cetylpyridinium Chloride	1	(0.1)	1	(0.1)	2	(0.1)
Chloramphenicol	1	(0.1)	1	(0.1)	2	(0.1)
Chlorhexidine	2	(0.1)	0		2	(0.1)
Chondroitin Sulfate Sodium	0		2	(0.1)	2	(0.1)
Chymotrypsin; Trypsin	1	(0.1)	1	(0.1)	2	(0.1)
Ciclopirox Olamine	2	(0.1)	0		2	(0.1)
Ciprofloxacin; Fluocinolone Acetonide	0		2	(0.1)	2	(0.1)
Clobetasol	2	(0.1)	0		2	(0.1)
Collagen	1	(0.1)	1	(0.1)	2	(0.1)
Cortisone Acetate	0		2	(0.1)	2	(0.1)
Curcuma Longa Rhizome	2	(0.1)	0		2	(0.1)
Dihydrocodeine	0		2	(0.1)	2	(0.1)
Dupilumab	1	(0.1)	1	(0.1)	2	(0.1)
Enoxolone	0		2	(0.1)	2	(0.1)
Ethanol	1	(0.1)	1	(0.1)	2	(0.1)
Etofenamate	0		2	(0.1)	2	(0.1)
Ferric Sodium Gluconate Complex	2	(0.1)	0		2	(0.1)
Flunarizine Dihydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Folinic Acid	2	(0.1)	0		2	(0.1)
Gentiana Lutea Root; Primula Spp. Flower; Rumex Spp. Herb; Sambucus Nigra Flower; Verbena Officinalis Herb	1	(0.1)	1	(0.1)	2	(0.1)
Ginkgo Biloba Extract	0		2	(0.1)	2	(0.1)
Ginkgo Biloba Leaf Dry Extract	1	(0.1)	1	(0.1)	2	(0.1)
Glucosamine	1	(0.1)	1	(0.1)	2	(0.1)
Glycerol	1	(0.1)	1	(0.1)	2	(0.1)
Hyaluronic Acid	2	(0.1)	0		2	(0.1)
Hydrocortisone Acetate	2	(0.1)	0		2	(0.1)
Hydrocortisone Sodium Succinate	0		2	(0.1)	2	(0.1)
Hydrocortisone; Oxytetracycline	0		2	(0.1)	2	(0.1)
Hydroxychloroquine	1	(0.1)	1	(0.1)	2	(0.1)
Hypromellose	2	(0.1)	0		2	(0.1)
Imdevimab	1	(0.1)	1	(0.1)	2	(0.1)
Imidazolyl Ethanamide Pentandioic Acid	2	(0.1)	0		2	(0.1)
Iron Dextran	2	(0.1)	0		2	(0.1)
Lamotrigine	0		2	(0.1)	2	(0.1)
Macrogol 400	2	(0.1)	0		2	(0.1)
Mannitol	0		2	(0.1)	2	(0.1)
Mephenoxalone	1	(0.1)	1	(0.1)	2	(0.1)
Mepyramine Maleate	1	(0.1)	1	(0.1)	2	(0.1)
Methadone	2	(0.1)	0		2	(0.1)
Molnupiravir	1	(0.1)	1	(0.1)	2	(0.1)
Monascus Purpureus	0		2	(0.1)	2	(0.1)
Mucopolysaccharide Polysulfuric Acid Ester	0		2	(0.1)	2	(0.1)
Naloxone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Neomycin Sulfate	1	(0.1)	1	(0.1)	2	(0.1)
Neostigmine	1	(0.1)	1	(0.1)	2	(0.1)
Other Respiratory System Products	1	(0.1)	1	(0.1)	2	(0.1)
Pectin	2	(0.1)	0		2	(0.1)
Plantago Ovata Husk	1	(0.1)	1	(0.1)	2	(0.1)
Potassium	1	(0.1)	1	(0.1)	2	(0.1)
Potassium Phosphate Dibasic; Potassium Phosphate Monobasic	1	(0.1)	1	(0.1)	2	(0.1)
Prednisolone Acetate	1	(0.1)	1	(0.1)	2	(0.1)
Retinol	1	(0.1)	1	(0.1)	2	(0.1)
Senna Alexandrina	1	(0.1)	1	(0.1)	2	(0.1)
Serenoa Repens	0		2	(0.1)	2	(0.1)
Sotrovimab	1	(0.1)	1	(0.1)	2	(0.1)
Steroids	0		2	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Tioconazole	2	(0.1)	0		2	(0.1)
Tobramycin	1	(0.1)	1	(0.1)	2	(0.1)
Vancomycin Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Vidarabine	0		2	(0.1)	2	(0.1)
Zinc Sulfate	0		2	(0.1)	2	(0.1)
Zingiber Officinale	0		2	(0.1)	2	(0.1)
Abrus Melanospermus Herb; Acanthopanax Gracilistylus Root Bark; Achyranthes Bidentata Root; Aconitum Carmichaelii Root Tuber; Aconitum Kusnezoffii Root Tuber; Adenosma Caeruleum Herb; Angelica Biserrata Roo	1	(0.1)	0		1	(0.0)
Abutilon Theophrasti Seed; Akebia Spp. Stem; Cynanchum Paniculatum Root With Rhizome; Dianthus Superbus Herb; Glechoma Longituba Herb; Glycyrrhiza Spp. Root With Rhizome; Lonicera Japonica Stem; Plantago Spp	0		1	(0.1)	1	(0.0)
Acetylcarnitine Hydrochloride	1	(0.1)	0		1	(0.0)
Acetylcysteine Sodium	1	(0.1)	0		1	(0.0)
Achyranthes Aspera; Chaenomeles Speciosa; Cibotium Barometz Rhizome; Clematis Chinensis Root With Rhizome; Codonopsis Javanica Root; Cullen Corylifolium Fruit; Curcuma Longa Rhizome; Epimedium Spp. Leaf; Ptya	0		1	(0.1)	1	(0.0)
Achyranthes Bidentata Root; Atractylodes Macrocephala, Rhizoma; Codonopsis Spp. Root; Glycyrrhiza Spp. Root With Rhizome; Ligusticum Chuanxiong Rhizome; Panax Notoginseng Root; Pheretima Spp.; Poria Cocos Sc	1	(0.1)	0		1	(0.0)
Aciclovir Sodium	0		1	(0.1)	1	(0.0)
Aconitum Carmichaelii Root Tuber; Aconitum Kusnezoffii Root Tuber; Phryma Leptostachya Herb; Plantago Spp. Herb; Saposhnikovia Divaricata Root; Schizonepeta Tenuifolia Herb; Sophora Flavescens Root	1	(0.1)	0		1	(0.0)
Aconitum Carmichaelii Root; Anemarrhena Asphodeloides Rhizome; Angelica Biserrata Root; Animal Bone Nos; Carthamus Tinctorius Flower; Cibotium Barometz Rhizome; Cinnamomum Cassia Twig; Clematis Spp. Root Wit	1	(0.1)	0		1	(0.0)
Aconitum Kusnezoffii Root Tuber; Acorus Calamus Rhizome; Asparagus Cochinchinensis Root Tuber; Borneol; Camphor; Curcuma Longa Rhizome; Euphorbia Pekinensis Root; Menthol; Methyl Salicylate; Polygonatum Odorat	1	(0.1)	0		1	(0.0)
Aconitum Kusnezoffii Root Tuber; Angelica Sinensis Root; Boswellia Spp. Resin; Commiphora Myrrha Resin; Flying Squirrel Feces; Herbal Nos; Liquidambar Formosana Resin; Momordica Cochinchinensis Seed; Musk; Phe	1	(0.1)	0		1	(0.0)
Aconitum Napellus; Citrullus Colocynthis; Gelsemium Sempervirens; Pulsatilla Pratensis; Verbascum Densiflorum	0		1	(0.1)	1	(0.0)
Acorus Calamus Var. Angustatus Rhizome; Angelica Dahurica Root; Angelica Spp. Root; Cinnamomum Cassia Twig; Ephedra Spp. Stem; Ligusticum Chuanxiong Rhizome; Mentha Canadensis Herb; Notopterygium Spp. Root W	0		1	(0.1)	1	(0.0)
Adenophora Spp. Root; Andrographis Paniculata Herb; Elaeagnus Pungens; Ephedra Spp. Herb; Papaver Somniferum; Platycodon Grandiflorus Root; Pseudostellaria Heterophylla Root; Stemona Spp. Root; Vitex Negundo	1	(0.1)	0		1	(0.0)
Aesculus Hippocastanum	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Aesculus Hippocastanum Extract	0		1	(0.1)	1	(0.0)
Aesculus Hippocastanum Seed	0		1	(0.1)	1	(0.0)
Alanine; Arginine; Aspartic Acid; Cysteine; Glutamic Acid; Glycine; Histidine; Isoleucine; Leucine; Lysine Acetate; Methionine; Phenylalanine; Proline; Serine; Threonine; Tryptophan, L-; Tyrosine; Valine	0		1	(0.1)	1	(0.0)
Alginic Acid; Silver	0		1	(0.1)	1	(0.0)
Alisma Orientale Tuber; Atractylodes Lancea Rhizome; Bupleurum Falcatum Root; Cinnamomum Cassia Bark; Glycyrrhiza Spp. Root; Panax Ginseng Root; Pinellia Ternata Tuber; Polyporus Umbellatus Sclerotium; Poria	1	(0.1)	0		1	(0.0)
Alisma Orientale Tuber; Cornus Officinalis Fruit; Dioscorea Spp. Rhizome; Paeonia X Suffruticosa Root Bark; Poria Cocos Sclerotium; Rehmannia Glutinosa Root	1	(0.1)	0		1	(0.0)
All Other Non-Therapeutic Products	0		1	(0.1)	1	(0.0)
Allium Cepa; Betula Spp. Leaf; Citrus Spp. Oil; Elymus Repens; Equisetum Spp.; Levisticum Spp. Root; Mentha X Piperita Oil; Petroselinum Crispum; Pinus Sylvestris Oil; Polygonum Aviculare; Salvia Spp. Oil; Solid	0		1	(0.1)	1	(0.0)
Aloe Spp.	1	(0.1)	0		1	(0.0)
Aloe Vera; Asini Corii Colla; Atractylodes Macrocephala; Citrus Spp. Unripe Fruit; Fallopia Multiflora; Lycium Barbarum Fruit; Panax Ginseng; Senna Tora Seed	0		1	(0.1)	1	(0.0)
Althaea Officinalis Extract; Sodium Bicarbonate	0		1	(0.1)	1	(0.0)
Althaea Officinalis; Calendula Officinalis; Glycyrrhiza Glabra	1	(0.1)	0		1	(0.0)
Aluminium Acetotartrate	0		1	(0.1)	1	(0.0)
Aluminium Silicate	1	(0.1)	0		1	(0.0)
Amantadine Hydrochloride	0		1	(0.1)	1	(0.0)
Amomum Spp. Fruit; Atractylodes Macrocephala, Rhizoma; Coix Lacryma-Jobi Subsp. Ma-Yuen Kernel; Dioscorea Oppositifolia Rhizome; Glycyrrhiza Spp. Root With Rhizome; Lablab Purpureus Seed; Nelumbo Nucifera S	0		1	(0.1)	1	(0.0)
Analgesics, Antipruritics, Astringents And Anti-Inflammatory Agents	0		1	(0.1)	1	(0.0)
Andrographis Paniculata; Bidens Pilosa Herb; Helicteres Angustifolia; Ilex Asprella Root; Isatis Tinctoria Leaf; Strobilanthes Cusia Root	0		1	(0.1)	1	(0.0)
Andrographolide; Humic Acid; Spirulina Spp.	1	(0.1)	0		1	(0.0)
Anemarrhena Asphodeloides Rhizome; Angelica Acutiloba Root; Atractylodes Spp. Rhizome; Bupleurum Falcatum Root; Citrus Aurantium Peel; Cyperus Rotundus Rhizome; Fritillaria Thunbergii Bulb; Glycyrrhiza Spp.	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Astragalus Spp. Root; Atractylodes Spp. Rhizome; Bupleurum Falcatum Root; Cimicifuga Spp. Rhizome; Citrus Aurantium Peel; Glycyrrhiza Spp. Root; Panax Ginseng Root; Zingiber Officinal	0		1	(0.1)	1	(0.0)
Angelica Acutiloba Root; Astragalus Spp. Root; Cinnamomum Cassia Bark; Glycyrrhiza Spp. Root; Magnolia Spp. Bark; Paeonia Lactiflora Root; Panax Ginseng Root; Pinellia Ternata Tuber; Zanthoxylum Piperitum Per	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Astragalus Spp. Root; Atractylodes Lancea Rhizome; Citrus Aurantium Peel; Glycyrrhiza Spp. Root;	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ophiopogon Japonicus Tuber; Panax Ginseng Root; Phellodendron Spp. Bark; Schisandra Ch						
Angelica Acutiloba Root; Atractylodes Spp. Rhizome; Calcium Sulfate; Cnidium Officinale Rhizome; Ephedra Spp. Herb; Forsythia Spp. Fruit; Gardenia Jasminoides Fruit; Glycyrrhiza Spp. Root; Mentha Canadensis H	0		1	(0.1)	1	(0.0)
Angelica Acutiloba Root; Bupleurum Falcatum Root; Cimicifuga Spp. Rhizome; Glycyrrhiza Spp. Root; Rheum Spp. Rhizome; Scutellaria Baicalensis Root	1	(0.1)	0		1	(0.0)
Angelica Acutiloba Root; Gardenia Jasminoides Fruit; Glycyrrhiza Spp. Root; Paeonia Lactiflora Root; Poria Cocos Sclerotium; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Angelica Dahurica Root; Astragalus Mongholicus Root; Chrysanthemum Indicum Flower; Glycyrrhiza Spp. Root With Rhizome; Ligusticum Chuanxiong Rhizome; Magnolia Spp. Flower Bud; Platycarya Strobilacea Infruct	1	(0.1)	0		1	(0.0)
Angelica Sinensis Root; Boswellia Sacra Bark Resin; Commiphora Myrrha Resin; Daemonorops Draco Fruit Resin; Drynaria Roosii Rhizome; Eupolyphaga Steleophaga; Pyrite; Rheum Spp. Root With Rhizome; Sodium Borat	0		1	(0.1)	1	(0.0)
Antiemetics And Antinauseants	1	(0.1)	0		1	(0.0)
Antihistamines	1	(0.1)	0		1	(0.0)
Armoracia Rusticana Root; Tropaeolum Majus	0		1	(0.1)	1	(0.0)
Artemisia Annua Herb; Bupleurum Chinense, Root; Forsythia Suspensa Fruit; Houttuynia Cordata Herb; Lonicera Japonica Flower Bud; Mentha Canadensis Herb; Platycodon Grandiflorus Root; Prunus Spp. Seed; Puerari	1	(0.1)	0		1	(0.0)
Artemisia Argyi Leaf	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Ferric Pyrophosphate	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Selenium; Zinc	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Aster Ageratoides Whole Plant; Firmiana Simplex Root; Metagentiana Rhodantha Whole Plant; Peucedanum Praeruptorum Root; Scleromitrion Diffusum Whole Plant; Scutellaria Baicalensis Root; Stemona Spp. Root Tu	0		1	(0.1)	1	(0.0)
Atractylodes Lancea Extract; Citrus Aurantium; Coptis Chinensis Extract; Coptis Deltoidea Extract; Coptis Japonica Extract; Coptis Teeta Extract; Mallotus Japonicus Extract; Syzygium Aromaticum Tincture; Tetr	1	(0.1)	0		1	(0.0)
Atractylodes Macrocephala	0		1	(0.1)	1	(0.0)
Atropa Belladonna Extract; Papaver Somniferum Latex	0		1	(0.1)	1	(0.0)
Atropa Belladonna Herb Liquid Extract; Bletilla Striata; Corydalis Yanhusuo; Glycyrrhiza Spp. Root With Rhizome; Paeonia Lactiflora Root; Panax Notoginseng; Poria Cocos; Sepiae Endoconcha	0		1	(0.1)	1	(0.0)
Atropine	1	(0.1)	0		1	(0.0)
Aucklandia Costus; Buffalo Horn; Carthamus Tinctorius Flower; Cow Bezoar; Gardenia Jasminoides; Melia Azedarach Fruit; Mercury Sulfide; Musk; Nelumbo Nucifera Seed; Ophiopogon Japonicus Root Tuber; Pterocarpus	1	(0.1)	0		1	(0.0)
Bacillus Coagulans	1	(0.1)	0		1	(0.0)
Bacillus Subtilis	1	(0.1)	0		1	(0.0)
Bacitracin Zinc; Neomycin Sulfate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Bacitracin Zinc; Neomycin Sulfate; Polymyxin B Sulfate	1	(0.1)	0		1	(0.0)
Bacteriophages	1	(0.1)	0		1	(0.0)
Benzalkonium Chloride	0		1	(0.1)	1	(0.0)
Benzalkonium Chloride; Eucalyptus Globulus Oil; Mentha X Piperita Oil; Menthol; Thymol	1	(0.1)	0		1	(0.0)
Benzathine Benzylpenicillin	0		1	(0.1)	1	(0.0)
Benzocaine; Menthol	0		1	(0.1)	1	(0.0)
Benzydamine Hydrochloride; Chlorhexidine Gluconate	1	(0.1)	0		1	(0.0)
Bepotastine	1	(0.1)	0		1	(0.0)
Berberine Hydrochloride; Borneol; Papaverine Hydrochloride; Rhus Spp. Galls; Sanguisorba Officinalis Root	1	(0.1)	0		1	(0.0)
Betamethasone Acetate	1	(0.1)	0		1	(0.0)
Betamethasone Sodium Phosphate; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Betamethasone Valerate; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Betula Spp. Leaf	1	(0.1)	0		1	(0.0)
Boric Acid	0		1	(0.1)	1	(0.0)
Borneol; Ligusticum Chuanxiong Rhizome	1	(0.1)	0		1	(0.0)
Boswellia Sacra Bark Resin; Carthamus Tinctorius Flower; Commiphora Myrrha Resin; Drynaria Roosii Rhizome; Periploca Sepium Root Bark; Pheretima Spp.; Stephania Tetrandra Root; Strychnos Nux-Vomica Seed	0		1	(0.1)	1	(0.0)
Botulinum Toxin Type A	1	(0.1)	0		1	(0.0)
Bovine Basic Fibroblast Growth Factor	0		1	(0.1)	1	(0.0)
Bromelains	1	(0.1)	0		1	(0.0)
Brompheniramine Maleate; Caffeine; Paracetamol	1	(0.1)	0		1	(0.0)
Buphenine	0		1	(0.1)	1	(0.0)
Bupleurum Falcatum Root; Calcium Sulfate; Glycyrrhiza Spp. Root; Panax Ginseng Root; Pinellia Ternata Tuber; Platycodon Grandiflorus Root; Scutellaria Baicalensis Root; Zingiber Officinale Rhizome; Ziziphus J	1	(0.1)	0		1	(0.0)
Cabergoline	0		1	(0.1)	1	(0.0)
Calcium Fluoride; Conium Maculatum; Hydrastis Canadensis; Thuja Occidentalis	0		1	(0.1)	1	(0.0)
Calcium Sulfate Dihydrate; Ephedra Spp. Stem; Glycyrrhiza Spp. Root With Rhizome; Papaver Somniferum Pericarp; Platycodon Grandiflorus Root; Prunus Spp. Seed; Raphanus Raphanistrum Subsp. Sativus Seed	0		1	(0.1)	1	(0.0)
Camphor	0		1	(0.1)	1	(0.0)
Cannabis Sativa	0		1	(0.1)	1	(0.0)
Cannabis Sativa Fruit; Citrus Spp. Unripe Fruit; Magnolia Spp. Bark; Paeonia Lactiflora Root; Prunus Spp. Seed; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Capsaicin	0		1	(0.1)	1	(0.0)
Capsicum Spp.; Gaultheria Procumbens; Mentha Arvensis	1	(0.1)	0		1	(0.0)
Carmellose Sodium; Silver	0		1	(0.1)	1	(0.0)
Carpronium Chloride	0		1	(0.1)	1	(0.0)
Centaurium Erythraea; Levisticum Officinale Root Powder; Rosmarinus Officinalis Leaf Dry Extract	0		1	(0.1)	1	(0.0)
Centella Asiatica	1	(0.1)	0		1	(0.0)
Centipede; Forsythia Suspensa; Lonicera Japonica Flower; Phellodendron Chinense; Taraxacum Mongolicum Herb	0		1	(0.1)	1	(0.0)
Cetraria Islandica; Malva Sylvestris	1	(0.1)	0		1	(0.0)
Cetylpyridinium Chloride; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Chloramphenicol; Collagenase	1	(0.1)	0		1	(0.0)
Chloramphenicol; Dexamethasone; Polymyxin B	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Sulfate						
Chlorphenamine Maleate; Ficus Microcarpa Leaf	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Paracetamol; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenoxamine Hydrochloride	1	(0.1)	0		1	(0.0)
Chondroitin Sulfate; Glucosamine Hydrochloride; Manganese Gluconate	1	(0.1)	0		1	(0.0)
Chondroitin Sulfate; Glucosamine Sulfate; Methylsulfonylmethane	0		1	(0.1)	1	(0.0)
Chondroitin Sulfate; Hyaluronate Sodium	0		1	(0.1)	1	(0.0)
Chondroitin; Glucosamine	1	(0.1)	0		1	(0.0)
Ciclopirox	1	(0.1)	0		1	(0.0)
Cinchocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Cinnamomum Camphora Oil; Foeniculum Vulgare; Rubia Tinctorum	1	(0.1)	0		1	(0.0)
Ciprofloxacin Hydrochloride; Dexamethasone	1	(0.1)	0		1	(0.0)
Ciprofloxacin Hydrochloride; Tinidazole	0		1	(0.1)	1	(0.0)
Citrus Aurantium	1	(0.1)	0		1	(0.0)
Clemastine	0		1	(0.1)	1	(0.0)
Clematis Spp. Extract; Prunella Vulgaris Extract; Trichosanthes Kirilowii Extract	0		1	(0.1)	1	(0.0)
Clioquinol	1	(0.1)	0		1	(0.0)
Clioquinol; Flumetasone Pivalate	0		1	(0.1)	1	(0.0)
Clobetasone Butyrate	0		1	(0.1)	1	(0.0)
Colistimethate Sodium; Erythromycin Lactobionate	0		1	(0.1)	1	(0.0)
Colistin Sulfate	0		1	(0.1)	1	(0.0)
Colostrum	1	(0.1)	0		1	(0.0)
Corticosteroids	1	(0.1)	0		1	(0.0)
Corydalis Bungeana Herb; Isatis Tinctoria Root; Scutellaria Baicalensis Root; Taraxacum Mongolicum Herb	0		1	(0.1)	1	(0.0)
Corydalis Bungeana; Isatis Indigotica; Scutellaria Baicalensis; Taraxacum Mongolicum	0		1	(0.1)	1	(0.0)
Creosote	1	(0.1)	0		1	(0.0)
Crotamiton; Hydrocortisone	0		1	(0.1)	1	(0.0)
Cucumis Melo Seed; Pig Bone	0		1	(0.1)	1	(0.0)
Cyclizine	0		1	(0.1)	1	(0.0)
Cysteine	1	(0.1)	0		1	(0.0)
Cysteine Hydrochloride; Glycyrrhizic Acid, Ammonium Salt	0		1	(0.1)	1	(0.0)
Dexamethasone Acetate	0		1	(0.1)	1	(0.0)
Dexamethasone Palmitate	0		1	(0.1)	1	(0.0)
Dexamethasone; Gentamicin Sulfate	0		1	(0.1)	1	(0.0)
Dexamethasone; Moxifloxacin Hydrochloride	0		1	(0.1)	1	(0.0)
Dexamethasone; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Dexamethasone; Ofloxacin	1	(0.1)	0		1	(0.0)
Dexpanthenol; Retinol; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Dicycloverine Hydrochloride; Mefenamic Acid	0		1	(0.1)	1	(0.0)
Docusate	0		1	(0.1)	1	(0.0)
Doxepin	1	(0.1)	0		1	(0.0)
Doxylamine Succinate	0		1	(0.1)	1	(0.0)
Drynaria Roosii	1	(0.1)	0		1	(0.0)
Durapatite	1	(0.1)	0		1	(0.0)
Dyclonine Hydrochloride	1	(0.1)	0		1	(0.0)
Echinacea Purpurea	0		1	(0.1)	1	(0.0)
Ectoine	1	(0.1)	0		1	(0.0)
Electrolytes Nos	0		1	(0.1)	1	(0.0)
Ephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Eucalyptus Spp. Oil; Mentha X Piperita Oil; Sulfanilamide; Sulfathiazole Sodium; Thymol	0		1	(0.1)	1	(0.0)
Fenoterol	1	(0.1)	0		1	(0.0)
Fenpiverinium; Metamizole; Pitofenone	1	(0.1)	0		1	(0.0)
Fenspiride	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Fexofenadine Hydrochloride; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Fluorescein	1	(0.1)	0		1	(0.0)
Formoterol Fumarate Dihydrate	1	(0.1)	0		1	(0.0)
Framycetin	0		1	(0.1)	1	(0.0)
Fusidate Sodium	1	(0.1)	0		1	(0.0)
Gardenia Jasminoides Fruit; Isatis Tinctoria Root; Phellodendron Chinense Bark; Scaphium Affine Seed; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Ginkgo Biloba Leaf Extract	1	(0.1)	0		1	(0.0)
Ginseng Nos; Minerals Nos; Vitamins Nos	0		1	(0.1)	1	(0.0)
Glucosamine Hydrochloride	1	(0.1)	0		1	(0.0)
Glycine	0		1	(0.1)	1	(0.0)
Glycine Max Seed Oil; Persea Americana Oil	1	(0.1)	0		1	(0.0)
Glycopyrronium	1	(0.1)	0		1	(0.0)
Glycopyrronium Bromide	0		1	(0.1)	1	(0.0)
Glycyrrhiza Glabra Root	0		1	(0.1)	1	(0.0)
Glycyrrhiza Glabra; Paeonia Lactiflora	1	(0.1)	0		1	(0.0)
Glycyrrhiza Spp. Root; Platycodon Grandiflorus Root	1	(0.1)	0		1	(0.0)
Glycyrrhiza Spp. Root; Rheum Spp. Rhizome	0		1	(0.1)	1	(0.0)
Gramicidin S	0		1	(0.1)	1	(0.0)
Gramicidin; Neomycin Sulfate; Nystatin; Triamcinolone	1	(0.1)	0		1	(0.0)
Gramicidin; Polymyxin B Sulfate	1	(0.1)	0		1	(0.0)
Hedera Helix Leaf	0		1	(0.1)	1	(0.0)
Hedera Helix; Thymus Vulgaris	0		1	(0.1)	1	(0.0)
Hexetidine	0		1	(0.1)	1	(0.0)
Homeopathics Nos	1	(0.1)	0		1	(0.0)
Hydrocortisone Valerate	1	(0.1)	0		1	(0.0)
Hydroxocobalamin	0		1	(0.1)	1	(0.0)
Hydroxycarbamide	1	(0.1)	0		1	(0.0)
Hydroxyquinoline	1	(0.1)	0		1	(0.0)
Hylan G-F 20	1	(0.1)	0		1	(0.0)
Hyoscine	0		1	(0.1)	1	(0.0)
Hypericum Perforatum	0		1	(0.1)	1	(0.0)
Inosine	1	(0.1)	0		1	(0.0)
Iodine	1	(0.1)	0		1	(0.0)
Isoconazole	0		1	(0.1)	1	(0.0)
Isoconazole Nitrate	1	(0.1)	0		1	(0.0)
Ketotifen Fumarate	0		1	(0.1)	1	(0.0)
Lactobacillus Fermentum	1	(0.1)	0		1	(0.0)
Lactobacillus Reuteri	0		1	(0.1)	1	(0.0)
Lespedeza Capitata	1	(0.1)	0		1	(0.0)
Levomenthol; Primula Spp. Root; Thymus Spp. Herb	0		1	(0.1)	1	(0.0)
Lidocaine Hydrochloride Monohydrate	1	(0.1)	0		1	(0.0)
Lincomycin	1	(0.1)	0		1	(0.0)
Linoleic Acid	1	(0.1)	0		1	(0.0)
Liquidambar Formosana Fruit	0		1	(0.1)	1	(0.0)
Lysimachia Christiniae Herb	0		1	(0.1)	1	(0.0)
Lysozyme	0		1	(0.1)	1	(0.0)
Lysozyme Chloride	1	(0.1)	0		1	(0.0)
Meldonium Dihydrate	0		1	(0.1)	1	(0.0)
Mentha X Piperita Oil; Menthol; Sarcandra Glabra Herb	0		1	(0.1)	1	(0.0)
Menthol; Methyl Salicylate	0		1	(0.1)	1	(0.0)
Methylethylpiridinol	0		1	(0.1)	1	(0.0)
Methylprednisolone Sodium Succinate	0		1	(0.1)	1	(0.0)
Methylsulfonylmethane	1	(0.1)	0		1	(0.0)
Milnacipran Hydrochloride	1	(0.1)	0		1	(0.0)
Mometasone Furoate Monohydrate	0		1	(0.1)	1	(0.0)
Momordica Charantia	1	(0.1)	0		1	(0.0)
Muscle Relaxants	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Myroxylon Balsamum Balsam	1	(0.1)	0		1	(0.0)
Naphazoline	0		1	(0.1)	1	(0.0)
Naphazoline Nitrate	1	(0.1)	0		1	(0.0)
Nicotinamide	1	(0.1)	0		1	(0.0)
Octenidine Hydrochloride	1	(0.1)	0		1	(0.0)
Ofloxacin Hydrochloride; Ornidazole	0		1	(0.1)	1	(0.0)
Omega-3 Nos	0		1	(0.1)	1	(0.0)
Orphenadrine	0		1	(0.1)	1	(0.0)
Other Antibacterials	0		1	(0.1)	1	(0.0)
Other Drugs For Disorders Of The Musculo-Skeletal System	0		1	(0.1)	1	(0.0)
Oxcarbazepine	1	(0.1)	0		1	(0.0)
Oxetacaine	0		1	(0.1)	1	(0.0)
Oxetacaine; Sucralfate	0		1	(0.1)	1	(0.0)
Oxiconazole Nitrate	1	(0.1)	0		1	(0.0)
Oxymetazoline	1	(0.1)	0		1	(0.0)
Paclitaxel	0		1	(0.1)	1	(0.0)
Palmidrol	0		1	(0.1)	1	(0.0)
Panax Quinquefolius Root	1	(0.1)	0		1	(0.0)
Papaver Somniferum; Platycodon Grandiflorus	1	(0.1)	0		1	(0.0)
Papaverine	1	(0.1)	0		1	(0.0)
Paraffin, Liquid; White Soft Paraffin	0		1	(0.1)	1	(0.0)
Passiflora Incarnata; Valeriana Officinalis	0		1	(0.1)	1	(0.0)
Penicillin Nos	1	(0.1)	0		1	(0.0)
Periplaneta Americana	1	(0.1)	0		1	(0.0)
Phellodendron Amurense Bark	1	(0.1)	0		1	(0.0)
Pheniramine	1	(0.1)	0		1	(0.0)
Phytomenadione	1	(0.1)	0		1	(0.0)
Pinus Spp. Tar; Sulfur	0		1	(0.1)	1	(0.0)
Piribedil	1	(0.1)	0		1	(0.0)
Polaprezinc	1	(0.1)	0		1	(0.0)
Polidocanol	0		1	(0.1)	1	(0.0)
Polihexanide; Undecylenamidopropyl Betaine	1	(0.1)	0		1	(0.0)
Polymyxin B Sulfate; Trimethoprim	0		1	(0.1)	1	(0.0)
Polymyxin B; Trimethoprim	1	(0.1)	0		1	(0.0)
Potassium Iodide	1	(0.1)	0		1	(0.0)
Potassium Phosphate Monobasic; Sodium Phosphate Dibasic; Sodium Phosphate Monobasic (Anhydrous)	1	(0.1)	0		1	(0.0)
Pramocaine	0		1	(0.1)	1	(0.0)
Prednisolone Valeroacetate	1	(0.1)	0		1	(0.0)
Pregnenolone	1	(0.1)	0		1	(0.0)
Probiotics Nos	1	(0.1)	0		1	(0.0)
Procaine Hydrochloride	0		1	(0.1)	1	(0.0)
Prochlorperazine Maleate	1	(0.1)	0		1	(0.0)
Promelase	0		1	(0.1)	1	(0.0)
Promethazine Hydrochloride	1	(0.1)	0		1	(0.0)
Pueraria Spp.	0		1	(0.1)	1	(0.0)
Quercus Salicina	0		1	(0.1)	1	(0.0)
Retinol; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Ribavirin	0		1	(0.1)	1	(0.0)
Riboflavin	1	(0.1)	0		1	(0.0)
Rifamycin Sodium	0		1	(0.1)	1	(0.0)
Ruscus Aculeatus	0		1	(0.1)	1	(0.0)
Rutoside	1	(0.1)	0		1	(0.0)
Sambucus Nigra	0		1	(0.1)	1	(0.0)
Sea Water	0		1	(0.1)	1	(0.0)
Secnidazole	0		1	(0.1)	1	(0.0)
Selenium	0		1	(0.1)	1	(0.0)
Senna Alexandrina Extract	0		1	(0.1)	1	(0.0)
Senna Alexandrina Glycoside Extract	1	(0.1)	0		1	(0.0)
Senna Spp.	0		1	(0.1)	1	(0.0)
Silybum Marianum	1	(0.1)	0		1	(0.0)
Sodium Bicarbonate; Sodium Gualenate Hydrate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Sodium Phosphate Dibasic	1	(0.1)	0		1	(0.0)
Sodium Phosphate Dibasic (Heptahydrate)	0		1	(0.1)	1	(0.0)
Sodium Phosphate Dibasic (Heptahydrate); Sodium Phosphate Monobasic (Monohydrate)	1	(0.1)	0		1	(0.0)
Sodium Phosphate Monobasic (Monohydrate)	0		1	(0.1)	1	(0.0)
Solidago Virgaurea Extract	1	(0.1)	0		1	(0.0)
Sorbitol	0		1	(0.1)	1	(0.0)
Strychnos Nux-Vomica Extract	1	(0.1)	0		1	(0.0)
Tetracaine Hydrochloride	1	(0.1)	0		1	(0.0)
Tetracycline	0		1	(0.1)	1	(0.0)
Tetracycline Hydrochloride	0		1	(0.1)	1	(0.0)
Tetryzoline	1	(0.1)	0		1	(0.0)
Tetryzoline Hydrochloride	1	(0.1)	0		1	(0.0)
Thiotriazoline	1	(0.1)	0		1	(0.0)
Tinidazole	1	(0.1)	0		1	(0.0)
Tocopherol	0		1	(0.1)	1	(0.0)
Triamcinolone Acetonide Acetate	1	(0.1)	0		1	(0.0)
Triclosan	1	(0.1)	0		1	(0.0)
Triticum Aestivum	0		1	(0.1)	1	(0.0)
Trypsin	0		1	(0.1)	1	(0.0)
Tyrothricin	0		1	(0.1)	1	(0.0)
Urogastrone	0		1	(0.1)	1	(0.0)
Vaccinium Macrocarpon	0		1	(0.1)	1	(0.0)
Vascular Endothelial Growth Factor Inhibitors	0		1	(0.1)	1	(0.0)
Vitamin B Nos	1	(0.1)	0		1	(0.0)
Xysmalobium Undulatum Root	1	(0.1)	0		1	(0.0)
Zingiber Officinale Rhizome	0		1	(0.1)	1	(0.0)
Insulin (Human), A10ab01	231	(12.3)	242	(12.9)	473	(12.6)
Insulin Aspart	137	(7.3)	142	(7.6)	279	(7.4)
Insulin Lispro	84	(4.5)	90	(4.8)	174	(4.6)
Insulin Human	6	(0.3)	7	(0.4)	13	(0.3)
Insulin	3	(0.2)	7	(0.4)	10	(0.3)
Insulin Porcine	1	(0.1)	3	(0.2)	4	(0.1)
Insulin Human; Insulin Human Injection, Isophane	3	(0.2)	0		3	(0.1)
Anilides, N02be	200	(10.6)	205	(10.9)	405	(10.8)
Paracetamol	173	(9.2)	187	(10.0)	360	(9.6)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Ephedrine Sulfate; Ethanol; Paracetamol	6	(0.3)	4	(0.2)	10	(0.3)
Caffeine; Paracetamol; Promethazine Methylene Disalicylate; Salicylamide	5	(0.3)	2	(0.1)	7	(0.2)
Dextromethorphan Hydrobromide; Guaifenesin; Paracetamol; Pseudoephedrine Hydrochloride	4	(0.2)	2	(0.1)	6	(0.2)
Ibuprofen; Paracetamol	2	(0.1)	4	(0.2)	6	(0.2)
Acetylsalicylic Acid; Caffeine; Paracetamol	0		3	(0.2)	3	(0.1)
Dextromethorphan Hydrobromide; Paracetamol; Phenylephrine Hydrochloride	0		3	(0.2)	3	(0.1)
Ascorbic Acid; Paracetamol; Pheniramine Maleate	0		2	(0.1)	2	(0.1)
Ascorbic Acid; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine Maleate; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan Hydrobromide; Guaifenesin; Paracetamol; Phenylephrine Hydrochloride	2	(0.1)	0		2	(0.1)
Dextromethorphan Hydrobromide; Paracetamol; Pseudoephedrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan; Guaifenesin; Paracetamol;	2	(0.1)	0		2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Phenylephrine						
Aceclofenac; Paracetamol	0		1	(0.1)	1	(0.0)
Aluminium Hydroxide Gel, Dried; Caffeine; Ibuprofen; Paracetamol	1	(0.1)	0		1	(0.0)
Amantadine Hydrochloride; Paracetamol	1	(0.1)	0		1	(0.0)
Ambroxol Hydrochloride; Chlorphenamine Maleate; Guaifenesin; Paracetamol; Phenylephrine Hydrochloride	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Caffeine; Chlorphenamine Maleate; Paracetamol	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Caffeine; Chlorphenamine Maleate; Paracetamol; Phenylephrine Hydrochloride; Salicylamide	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Caffeine; Paracetamol; Phenylephrine Hydrochloride; Terpin	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Paracetamol	0		1	(0.1)	1	(0.0)
Bromhexine; Chlorphenamine; Guaifenesin; Paracetamol; Phenylephrine	0		1	(0.1)	1	(0.0)
Caffeine; Chlorphenamine Maleate; Cow Bezoar; Paracetamol	1	(0.1)	0		1	(0.0)
Caffeine; Chlorphenamine Maleate; Paracetamol	1	(0.1)	0		1	(0.0)
Caffeine; Diphenhydramine; Paracetamol; Phenylephrine	0		1	(0.1)	1	(0.0)
Caffeine; Mepyramine Maleate; Paracetamol	1	(0.1)	0		1	(0.0)
Caffeine; Paracetamol	0		1	(0.1)	1	(0.0)
Caffeine; Paracetamol; Propyphenazone	1	(0.1)	0		1	(0.0)
Cetirizine; Paracetamol; Phenylephrine	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dextromethorphan; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Paracetamol; Pseudoephedrine	0		1	(0.1)	1	(0.0)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Paracetamol; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine; Paracetamol	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Doxylamine Succinate; Ephedrine Sulfate; Paracetamol	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin; Paracetamol	0		1	(0.1)	1	(0.0)
Dextromethorphan Hydrobromide; Paracetamol	1	(0.1)	0		1	(0.0)
Diclofenac; Paracetamol	0		1	(0.1)	1	(0.0)
Diphenhydramine Hydrochloride; Paracetamol; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Diphenhydramine; Paracetamol; Phenylephrine	1	(0.1)	0		1	(0.0)
Sulfonylureas, A10bb	191	(10.2)	182	(9.7)	373	(9.9)
Gliclazide	107	(5.7)	107	(5.7)	214	(5.7)
Glimepiride	40	(2.1)	51	(2.7)	91	(2.4)
Glipizide	29	(1.5)	13	(0.7)	42	(1.1)
Glibenclamide	16	(0.8)	11	(0.6)	27	(0.7)
Gliquidone	1	(0.1)	1	(0.1)	2	(0.1)
Influenza Vaccines, J07bb	182	(9.7)	152	(8.1)	334	(8.9)
Influenza Vaccine	145	(7.7)	124	(6.6)	269	(7.2)
Influenza Vaccine Inact Split 4v	13	(0.7)	13	(0.7)	26	(0.7)
Influenza Vaccine Inact Sag 4v	10	(0.5)	7	(0.4)	17	(0.5)
Influenza Vaccine Inact Sag 3v	9	(0.5)	3	(0.2)	12	(0.3)
Influenza Vaccine Inact Split 3v	4	(0.2)	4	(0.2)	8	(0.2)
Influenza Vaccine Inact Split	0		1	(0.1)	1	(0.0)
Influenza Vaccine Rha 4v (Baculovirus)	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Anticholinergics, S01fa	146	(7.8)	161	(8.6)	307	(8.2)
Phenylephrine Hydrochloride; Tropicamide	97	(5.2)	108	(5.8)	205	(5.5)
Tropicamide	49	(2.6)	51	(2.7)	100	(2.7)
Cyclopentolate	1	(0.1)	1	(0.1)	2	(0.1)
Phenylephrine; Tropicamide	0		2	(0.1)	2	(0.1)
Cyclopentolate Hydrochloride	0		1	(0.1)	1	(0.0)
Hmg Coa Reductase Inhibitors, C10aa	140	(7.5)	152	(8.1)	292	(7.8)
Atorvastatin	54	(2.9)	70	(3.7)	124	(3.3)
Rosuvastatin	38	(2.0)	33	(1.8)	71	(1.9)
Atorvastatin Calcium	18	(1.0)	26	(1.4)	44	(1.2)
Rosuvastatin Calcium	18	(1.0)	16	(0.8)	34	(0.9)
Simvastatin	8	(0.4)	8	(0.4)	16	(0.4)
Pravastatin	9	(0.5)	3	(0.2)	12	(0.3)
Pitavastatin Calcium	1	(0.1)	2	(0.1)	3	(0.1)
Pitavastatin	2	(0.1)	0		2	(0.1)
Pravastatin Sodium	2	(0.1)	0		2	(0.1)
Propionic Acid Derivatives, M01ae	143	(7.6)	146	(7.8)	289	(7.7)
Ibuprofen	67	(3.6)	67	(3.6)	134	(3.6)
Loxoprofen Sodium Dihydrate	28	(1.5)	25	(1.3)	53	(1.4)
Ketoprofen	21	(1.1)	12	(0.6)	33	(0.9)
Naproxen	15	(0.8)	12	(0.6)	27	(0.7)
Naproxen Sodium	8	(0.4)	15	(0.8)	23	(0.6)
Loxoprofen Sodium	12	(0.6)	9	(0.5)	21	(0.6)
Dexketoprofen	5	(0.3)	10	(0.5)	15	(0.4)
Flurbiprofen	3	(0.2)	6	(0.3)	9	(0.2)
Dexketoprofen Trometamol	1	(0.1)	3	(0.2)	4	(0.1)
Loxoprofen	1	(0.1)	3	(0.2)	4	(0.1)
Pranoprofen	1	(0.1)	2	(0.1)	3	(0.1)
Zaltoprofen	1	(0.1)	2	(0.1)	3	(0.1)
Apronal; Caffeine; Ibuprofen	0		2	(0.1)	2	(0.1)
Arginine Hydrochloride; Ibuprofen	1	(0.1)	1	(0.1)	2	(0.1)
Ibuprofen; Pseudoephedrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Ketoprofen Lysine	1	(0.1)	1	(0.1)	2	(0.1)
Aluminium Magnesium Silicate; Apronal; Caffeine; Loxoprofen Sodium Dihydrate	0		1	(0.1)	1	(0.0)
Benfotiamine; Caffeine; Chlorphenamine Maleate; Ibuprofen; Methylephedrine Hydrochloride-Dl; Riboflavin; Sulfogaiacol; Tipepidine Hibenzate	0		1	(0.1)	1	(0.0)
Chlorphenamine Maleate; Ibuprofen; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Dexibuprofen	1	(0.1)	0		1	(0.0)
Esflurbiprofen	1	(0.1)	0		1	(0.0)
Esomeprazole Magnesium; Naproxen	0		1	(0.1)	1	(0.0)
Pelubiprofen	0		1	(0.1)	1	(0.0)
Tiaprofenic Acid	1	(0.1)	0		1	(0.0)
Biguanides, A10ba	127	(6.8)	109	(5.8)	236	(6.3)
Metformin	80	(4.3)	81	(4.3)	161	(4.3)
Metformin Hydrochloride	47	(2.5)	28	(1.5)	75	(2.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Proton Pump Inhibitors, A02bc	93	(5.0)	96	(5.1)	189	(5.0)
Omeprazole	29	(1.5)	23	(1.2)	52	(1.4)
Pantoprazole Sodium Sesquihydrate	21	(1.1)	22	(1.2)	43	(1.1)
Pantoprazole	21	(1.1)	17	(0.9)	38	(1.0)
Lansoprazole	6	(0.3)	10	(0.5)	16	(0.4)
Esomeprazole Magnesium	8	(0.4)	7	(0.4)	15	(0.4)
Esomeprazole	6	(0.3)	4	(0.2)	10	(0.3)
Rabeprazole Sodium	2	(0.1)	8	(0.4)	10	(0.3)
Vonoprazan Fumarate	3	(0.2)	4	(0.2)	7	(0.2)
Dexlansoprazole	0		3	(0.2)	3	(0.1)
Domperidone; Pantoprazole Sodium Sesquihydrate	1	(0.1)	2	(0.1)	3	(0.1)
Rabeprazole	1	(0.1)	2	(0.1)	3	(0.1)
Domperidone; Pantoprazole	0		2	(0.1)	2	(0.1)
Domperidone; Rabeprazole	1	(0.1)	1	(0.1)	2	(0.1)
Domperidone; Esomeprazole	0		1	(0.1)	1	(0.0)
Domperidone; Omeprazole	1	(0.1)	0		1	(0.0)
Esomeprazole Magnesium Dihydrate	1	(0.1)	0		1	(0.0)
Esomeprazole Magnesium Trihydrate	1	(0.1)	0		1	(0.0)
Ilaprazole	1	(0.1)	0		1	(0.0)
Omeprazole Sodium	0		1	(0.1)	1	(0.0)
Glucagon-Like Peptide-1 (Glp-1) Analogues, A10bj	95	(5.0)	93	(5.0)	188	(5.0)
Semaglutide	57	(3.0)	54	(2.9)	111	(3.0)
Dulaglutide	27	(1.4)	34	(1.8)	61	(1.6)
Liraglutide	10	(0.5)	5	(0.3)	15	(0.4)
Exenatide	3	(0.2)	2	(0.1)	5	(0.1)
Lixisenatide	0		1	(0.1)	1	(0.0)
Sodium-Glucose Co-Transporter 2 (Sglt2) Inhibitors, A10bk	98	(5.2)	89	(4.7)	187	(5.0)
Empagliflozin	52	(2.8)	43	(2.3)	95	(2.5)
Dapagliflozin	21	(1.1)	27	(1.4)	48	(1.3)
Dapagliflozin Propanediol Monohydrate	20	(1.1)	12	(0.6)	32	(0.8)
Canagliflozin	7	(0.4)	3	(0.2)	10	(0.3)
Ertugliflozin	0		2	(0.1)	2	(0.1)
Ipragliflozin L-Proline	1	(0.1)	1	(0.1)	2	(0.1)
Luseogliflozin	0		1	(0.1)	1	(0.0)
Acetic Acid Derivatives And Related Substances, M01ab	81	(4.3)	88	(4.7)	169	(4.5)
Diclofenac	26	(1.4)	28	(1.5)	54	(1.4)
Diclofenac Sodium	25	(1.3)	25	(1.3)	50	(1.3)
Ketorolac	7	(0.4)	8	(0.4)	15	(0.4)
Aceclofenac	8	(0.4)	6	(0.3)	14	(0.4)
Ketorolac Tromethamine	5	(0.3)	8	(0.4)	13	(0.3)
Bromfenac Sodium	3	(0.2)	9	(0.5)	12	(0.3)
Indometacin	3	(0.2)	7	(0.4)	10	(0.3)
Etodolac	5	(0.3)	2	(0.1)	7	(0.2)
Acemetacin	2	(0.1)	2	(0.1)	4	(0.1)
Diclofenac Diethylamine	0		2	(0.1)	2	(0.1)
Diclofenac Potassium	2	(0.1)	0		2	(0.1)
Diclofenac Sodium; Serrapeptase	1	(0.1)	1	(0.1)	2	(0.1)
Bromfenac	1	(0.1)	0		1	(0.0)
Diclofenac Epolamine	1	(0.1)	0		1	(0.0)
Diclofenac Sodium; Lidocaine	0		1	(0.1)	1	(0.0)
Diclofenac Sodium; Misoprostol	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Angiotensin Ii Receptor Blockers (Arbs), Plain, C09ca	78	(4.2)	84	(4.5)	162	(4.3)
Losartan	27	(1.4)	29	(1.5)	56	(1.5)
Valsartan	12	(0.6)	20	(1.1)	32	(0.8)
Telmisartan	15	(0.8)	14	(0.8)	29	(0.8)
Candesartan	8	(0.4)	4	(0.2)	12	(0.3)
Irbesartan	4	(0.2)	7	(0.4)	11	(0.3)
Olmesartan	4	(0.2)	4	(0.2)	8	(0.2)
Candesartan Cilexetil	4	(0.2)	2	(0.1)	6	(0.2)
Losartan Potassium	2	(0.1)	3	(0.2)	5	(0.1)
Olmesartan Medoxomil	1	(0.1)	3	(0.2)	4	(0.1)
Azilsartan	3	(0.2)	0		3	(0.1)
Penicillins With Extended Spectrum, J01ca	79	(4.2)	76	(4.0)	155	(4.1)
Amoxicillin	72	(3.8)	60	(3.2)	132	(3.5)
Amoxicillin Trihydrate	7	(0.4)	15	(0.8)	22	(0.6)
Amoxicillin Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Carbenicillin Disodium	0		1	(0.1)	1	(0.0)
Pivmecillinam Hydrochloride	0		1	(0.1)	1	(0.0)
Platelet Aggregation Inhibitors Excl. Heparin, B01ac	70	(3.7)	69	(3.7)	139	(3.7)
Acetylsalicylic Acid	50	(2.7)	54	(2.9)	104	(2.8)
Clopidogrel	12	(0.6)	10	(0.5)	22	(0.6)
Clopidogrel Bisulfate	14	(0.7)	6	(0.3)	20	(0.5)
Ticagrelor	3	(0.2)	5	(0.3)	8	(0.2)
Prasugrel	3	(0.2)	3	(0.2)	6	(0.2)
Acetylsalicylic Acid; Magnesium Hydroxide	2	(0.1)	2	(0.1)	4	(0.1)
Prasugrel Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Acetylsalicylate Lysine	1	(0.1)	1	(0.1)	2	(0.1)
Dipyridamole	1	(0.1)	0		1	(0.0)
Salicylic Acid	1	(0.1)	0		1	(0.0)
Salicylic Acid; White Soft Paraffin	1	(0.1)	0		1	(0.0)
Tirofiban	1	(0.1)	0		1	(0.0)
Triflusal	0		1	(0.1)	1	(0.0)
Ace Inhibitors, Plain, C09aa	65	(3.5)	58	(3.1)	123	(3.3)
Ramipril	20	(1.1)	16	(0.8)	36	(1.0)
Lisinopril	19	(1.0)	13	(0.7)	32	(0.8)
Perindopril	12	(0.6)	11	(0.6)	23	(0.6)
Enalapril	7	(0.4)	7	(0.4)	14	(0.4)
Captopril	2	(0.1)	9	(0.5)	11	(0.3)
Enalapril Maleate	1	(0.1)	1	(0.1)	2	(0.1)
Perindopril Arginine	0		2	(0.1)	2	(0.1)
Alacepril	1	(0.1)	0		1	(0.0)
Benazepril	1	(0.1)	0		1	(0.0)
Benazepril Hydrochloride	1	(0.1)	0		1	(0.0)
Imidapril Hydrochloride	0		1	(0.1)	1	(0.0)
Lisinopril Dihydrate	1	(0.1)	0		1	(0.0)
Perindopril Erbumine	1	(0.1)	0		1	(0.0)
Quinapril Hydrochloride	0		1	(0.1)	1	(0.0)
Trandolapril	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Dihydropyridine Derivatives, C08ca	59	(3.1)	63	(3.4)	122	(3.2)
Amlodipine	39	(2.1)	34	(1.8)	73	(1.9)
Amlodipine Besilate	10	(0.5)	12	(0.6)	22	(0.6)
Nifedipine	5	(0.3)	7	(0.4)	12	(0.3)
Lercanidipine	1	(0.1)	5	(0.3)	6	(0.2)
Lercanidipine Hydrochloride	3	(0.2)	3	(0.2)	6	(0.2)
Lacidipine	1	(0.1)	2	(0.1)	3	(0.1)
Benidipine Hydrochloride	0		2	(0.1)	2	(0.1)
Amlodipine Maleate	1	(0.1)	0		1	(0.0)
Azelnidipine	1	(0.1)	0		1	(0.0)
Cilnidipine	1	(0.1)	0		1	(0.0)
Felodipine	1	(0.1)	0		1	(0.0)
Nicardipine	0		1	(0.1)	1	(0.0)
Other Antihistamines For Systemic Use, R06ax	56	(3.0)	58	(3.1)	114	(3.0)
Loratadine	14	(0.7)	24	(1.3)	38	(1.0)
Olopatadine Hydrochloride	9	(0.5)	9	(0.5)	18	(0.5)
Bilastine	8	(0.4)	9	(0.5)	17	(0.5)
Fexofenadine Hydrochloride	10	(0.5)	5	(0.3)	15	(0.4)
Desloratadine	7	(0.4)	7	(0.4)	14	(0.4)
Epinastine Hydrochloride	5	(0.3)	6	(0.3)	11	(0.3)
Rupatadine Fumarate	6	(0.3)	1	(0.1)	7	(0.2)
Fexofenadine	1	(0.1)	3	(0.2)	4	(0.1)
Epinastine	2	(0.1)	1	(0.1)	3	(0.1)
Ebastine	2	(0.1)	0		2	(0.1)
Olopatadine	1	(0.1)	1	(0.1)	2	(0.1)
Triprolidine Hydrochloride	0		2	(0.1)	2	(0.1)
Astemizole	0		1	(0.1)	1	(0.0)
Desloratadine Citrate Disodium	1	(0.1)	0		1	(0.0)
Loratadine Hydrochloride	0		1	(0.1)	1	(0.0)
Rupatadine	0		1	(0.1)	1	(0.0)
Beta Blocking Agents, Selective, C07ab	66	(3.5)	46	(2.5)	112	(3.0)
Metoprolol	18	(1.0)	14	(0.8)	32	(0.8)
Bisoprolol	13	(0.7)	11	(0.6)	24	(0.6)
Bisoprolol Fumarate	14	(0.7)	9	(0.5)	23	(0.6)
Metoprolol Succinate	10	(0.5)	2	(0.1)	12	(0.3)
Nebivolol	4	(0.2)	8	(0.4)	12	(0.3)
Metoprolol Tartrate	5	(0.3)	2	(0.1)	7	(0.2)
Nebivolol Hydrochloride	5	(0.3)	2	(0.1)	7	(0.2)
Atenolol	3	(0.2)	0		3	(0.1)
Betaxolol Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Beta Blocking Agents	1	(0.1)	0		1	(0.0)
Insulins And Analogues For Injection, Intermediate-Acting, A10ac	49	(2.6)	60	(3.2)	109	(2.9)
Insulin Human Injection, Isophane	38	(2.0)	47	(2.5)	85	(2.3)
Isophane Insulin	11	(0.6)	10	(0.5)	21	(0.6)
Insulin Isophane Porcine	0		2	(0.1)	2	(0.1)
Insulin Lispro Protamine Suspension	0		2	(0.1)	2	(0.1)
Vitamin D And Analogues, A11cc	45	(2.4)	57	(3.0)	102	(2.7)
Colecalciferol	34	(1.8)	41	(2.2)	75	(2.0)
Vitamin D Nos	8	(0.4)	13	(0.7)	21	(0.6)
Ergocalciferol	2	(0.1)	2	(0.1)	4	(0.1)
Alfacalcidol	1	(0.1)	1	(0.1)	2	(0.1)
Colecalciferol-Cholesterin	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Third-Generation Cephalosporins, J01dd	51	(2.7)	50	(2.7)	101	(2.7)
Ceftriaxone	11	(0.6)	9	(0.5)	20	(0.5)
Ceftriaxone Sodium	13	(0.7)	7	(0.4)	20	(0.5)
Cefdinir	13	(0.7)	5	(0.3)	18	(0.5)
Cefixime	8	(0.4)	5	(0.3)	13	(0.3)
Cefcapene Pivoxil Hydrochloride Hydrate	3	(0.2)	5	(0.3)	8	(0.2)
Cefcapene Pivoxil Hydrochloride	2	(0.1)	5	(0.3)	7	(0.2)
Cefpodoxime Proxetil	2	(0.1)	5	(0.3)	7	(0.2)
Ceftazidime	1	(0.1)	3	(0.2)	4	(0.1)
Cefditoren Pivoxil	1	(0.1)	2	(0.1)	3	(0.1)
Cefpodoxime	0		3	(0.2)	3	(0.1)
Ceftriaxone Sodium Sesquaterhydrate	1	(0.1)	2	(0.1)	3	(0.1)
Cefixime Trihydrate	1	(0.1)	1	(0.1)	2	(0.1)
Cefoperazone; Sulbactam	1	(0.1)	0		1	(0.0)
Cefotaxime; Sulbactam	1	(0.1)	0		1	(0.0)
Cefpodoxime Proxetil; Clavulanate Potassium	0		1	(0.1)	1	(0.0)
Ceftizoxime Sodium	0		1	(0.1)	1	(0.0)
Ceftriaxone Sodium; Tazobactam Sodium	0		1	(0.1)	1	(0.0)
Heparin Group, B01ab	51	(2.7)	39	(2.1)	90	(2.4)
Enoxaparin Sodium	25	(1.3)	17	(0.9)	42	(1.1)
Heparin	10	(0.5)	10	(0.5)	20	(0.5)
Enoxaparin	9	(0.5)	7	(0.4)	16	(0.4)
Nadroparin Calcium	6	(0.3)	3	(0.2)	9	(0.2)
Sulodexide	1	(0.1)	1	(0.1)	2	(0.1)
Certoparin Sodium	0		1	(0.1)	1	(0.0)
Heparin Porcine	1	(0.1)	0		1	(0.0)
Heparin Sodium	1	(0.1)	0		1	(0.0)
Nadroparin	1	(0.1)	0		1	(0.0)
Tinzaparin Sodium	0		1	(0.1)	1	(0.0)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors, J01cr	49	(2.6)	40	(2.1)	89	(2.4)
Amoxicillin; Clavulanic Acid	26	(1.4)	18	(1.0)	44	(1.2)
Amoxicillin Trihydrate; Clavulanate Potassium	12	(0.6)	11	(0.6)	23	(0.6)
Amoxicillin; Clavulanate Potassium	5	(0.3)	6	(0.3)	11	(0.3)
Piperacillin Sodium; Tazobactam Sodium	3	(0.2)	4	(0.2)	7	(0.2)
Amoxicillin Sodium; Clavulanate Potassium	3	(0.2)	2	(0.1)	5	(0.1)
Piperacillin; Tazobactam	1	(0.1)	1	(0.1)	2	(0.1)
Ampicillin; Sulbactam	0		1	(0.1)	1	(0.0)
Combinations Of Penicillins, Incl. Beta-Lactamase Inhibitors	1	(0.1)	0		1	(0.0)
Dipeptidyl Peptidase 4 (Dpp-4) Inhibitors, A10bh	41	(2.2)	48	(2.6)	89	(2.4)
Sitagliptin	11	(0.6)	11	(0.6)	22	(0.6)
Linagliptin	9	(0.5)	11	(0.6)	20	(0.5)
Vildagliptin	5	(0.3)	15	(0.8)	20	(0.5)
Sitagliptin Phosphate	12	(0.6)	7	(0.4)	19	(0.5)
Alogliptin	0		3	(0.2)	3	(0.1)
Teneligliptin	2	(0.1)	0		2	(0.1)
Gemigliptin	1	(0.1)	0		1	(0.0)
Saxagliptin	1	(0.1)	0		1	(0.0)
Saxagliptin Hydrochloride	1	(0.1)	0		1	(0.0)
Teneligliptin Hydrobromide	0		1	(0.1)	1	(0.0)
Teneligliptin Hydrobromide Hydrate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Phenylephrine, C01ca06	37	(2.0)	44	(2.3)	81	(2.2)
Phenylephrine Hydrochloride	31	(1.6)	37	(2.0)	68	(1.8)
Phenylephrine	5	(0.3)	7	(0.4)	12	(0.3)
Chlorphenamine Maleate; Ibuprofen; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Paracetamol; Phenylephrine Hydrochloride	0		1	(0.1)	1	(0.0)
Glucocorticoids, H02ab	35	(1.9)	34	(1.8)	69	(1.8)
Prednisone	8	(0.4)	13	(0.7)	21	(0.6)
Dexamethasone	9	(0.5)	9	(0.5)	18	(0.5)
Methylprednisolone	6	(0.3)	5	(0.3)	11	(0.3)
Deflazacort	3	(0.2)	2	(0.1)	5	(0.1)
Methylprednisolone Acetate	2	(0.1)	3	(0.2)	5	(0.1)
Prednisolone	3	(0.2)	2	(0.1)	5	(0.1)
Cortisone	3	(0.2)	1	(0.1)	4	(0.1)
Dexamethasone Sodium Phosphate	1	(0.1)	2	(0.1)	3	(0.1)
Prednisolone Acetate	1	(0.1)	1	(0.1)	2	(0.1)
Prednisolone Valeroacetate	1	(0.1)	0		1	(0.0)
Beta-Lactamase Inhibitors, J01cg	33	(1.8)	35	(1.9)	68	(1.8)
Clavulanic Acid	31	(1.6)	24	(1.3)	55	(1.5)
Clavulanate Potassium	2	(0.1)	10	(0.5)	12	(0.3)
Tazobactam	0		1	(0.1)	1	(0.0)
Fibrates, C10ab	36	(1.9)	31	(1.6)	67	(1.8)
Fenofibrate	19	(1.0)	18	(1.0)	37	(1.0)
Bezafibrate	15	(0.8)	9	(0.5)	24	(0.6)
Gemfibrozil	0		3	(0.2)	3	(0.1)
Fenofibric Acid	2	(0.1)	0		2	(0.1)
Ciprofibrate	0		1	(0.1)	1	(0.0)
First-Generation Cephalosporins, J01db	32	(1.7)	35	(1.9)	67	(1.8)
Cefalexin	21	(1.1)	19	(1.0)	40	(1.1)
Cefazolin	4	(0.2)	8	(0.4)	12	(0.3)
Cefazolin Sodium	6	(0.3)	4	(0.2)	10	(0.3)
Cefadroxil	4	(0.2)	3	(0.2)	7	(0.2)
Cefazedone Sodium	0		1	(0.1)	1	(0.0)
Pregabalin, N03ax16	36	(1.9)	31	(1.6)	67	(1.8)
Pregabalin	35	(1.9)	31	(1.6)	66	(1.8)
Mecobalamin; Pregabalin	1	(0.1)	0		1	(0.0)
Coxibs, M01ah	35	(1.9)	30	(1.6)	65	(1.7)
Celecoxib	20	(1.1)	17	(0.9)	37	(1.0)
Etoricoxib	15	(0.8)	10	(0.5)	25	(0.7)
Imrecoxib	0		2	(0.1)	2	(0.1)
Parecoxib Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Parecoxib	0		1	(0.1)	1	(0.0)
Other Centrally Acting Agents, M03bx	27	(1.4)	31	(1.6)	58	(1.5)
Thiocolchicoside	5	(0.3)	9	(0.5)	14	(0.4)
Cyclobenzaprine	9	(0.5)	3	(0.2)	12	(0.3)
Tizanidine Hydrochloride	6	(0.3)	3	(0.2)	9	(0.2)
Tizanidine	1	(0.1)	5	(0.3)	6	(0.2)
Cyclobenzaprine Hydrochloride	1	(0.1)	4	(0.2)	5	(0.1)
Eperisone Hydrochloride	4	(0.2)	1	(0.1)	5	(0.1)
Baclofen	0		4	(0.2)	4	(0.1)
Fenyramidol Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Etodolac; Thiocolchicoside	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Opium Alkaloids And Derivatives, R05da	28	(1.5)	29	(1.5)	57	(1.5)
Dextromethorphan Hydrobromide	7	(0.4)	9	(0.5)	16	(0.4)
Codeine Phosphate	7	(0.4)	3	(0.2)	10	(0.3)
Codeine	4	(0.2)	5	(0.3)	9	(0.2)
Dextromethorphan	3	(0.2)	6	(0.3)	9	(0.2)
Chlorphenamine Maleate; Dihydrocodeine Phosphate; Methylephedrine Hydrochloride-Dl	2	(0.1)	1	(0.1)	3	(0.1)
Brompheniramine; Dextromethorphan; Pseudoephedrine	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Phenylephrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Codeine Phosphate; Promethazine Hydrochloride	2	(0.1)	0		2	(0.1)
Dextromethorphan Hydrobromide; Promethazine Hydrochloride	0		2	(0.1)	2	(0.1)
Brompheniramine Maleate; Dextromethorphan Hydrobromide; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dextromethorphan Hydrobromide	1	(0.1)	0		1	(0.0)
Chlorphenamine; Dextromethorphan	0		1	(0.1)	1	(0.0)
Codeine; Promethazine	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Doxylamine Succinate	0		1	(0.1)	1	(0.0)
Noscapine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02bx	30	(1.6)	26	(1.4)	56	(1.5)
Rebamipide	24	(1.3)	21	(1.1)	45	(1.2)
Bismuth Subsalicylate	1	(0.1)	4	(0.2)	5	(0.1)
Troxipide	1	(0.1)	2	(0.1)	3	(0.1)
Calcium Carbonate; Sodium Alginate; Sodium Bicarbonate	1	(0.1)	0		1	(0.0)
Ecabet Monosodium	1	(0.1)	0		1	(0.0)
Levoglutamide; Sodium Gualenate	1	(0.1)	0		1	(0.0)
Tripotassium Dicitratobismuthate	1	(0.1)	0		1	(0.0)
Other Opioids, N02ax	24	(1.3)	32	(1.7)	56	(1.5)
Tramadol	18	(1.0)	25	(1.3)	43	(1.1)
Tramadol Hydrochloride	5	(0.3)	7	(0.4)	12	(0.3)
Tapentadol	1	(0.1)	1	(0.1)	2	(0.1)
Tapentadol Hydrochloride	0		1	(0.1)	1	(0.0)
Sulfonamides, Plain, C03ca	28	(1.5)	26	(1.4)	54	(1.4)
Furosemide	22	(1.2)	23	(1.2)	45	(1.2)
Torasemide	4	(0.2)	2	(0.1)	6	(0.2)
Azosemide	3	(0.2)	0		3	(0.1)
Bumetanide	1	(0.1)	1	(0.1)	2	(0.1)
Piperazine Derivatives, R06ae	26	(1.4)	27	(1.4)	53	(1.4)
Cetirizine Hydrochloride	10	(0.5)	7	(0.4)	17	(0.5)
Cetirizine	6	(0.3)	9	(0.5)	15	(0.4)
Levocetirizine Dihydrochloride	7	(0.4)	7	(0.4)	14	(0.4)
Levocetirizine	3	(0.2)	4	(0.2)	7	(0.2)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Natural Opium Alkaloids, N02aa	27	(1.4)	23	(1.2)	50	(1.3)
Hydrocodone	14	(0.7)	4	(0.2)	18	(0.5)
Oxycodone	6	(0.3)	7	(0.4)	13	(0.3)
Dihydrocodeine Phosphate	0		4	(0.2)	4	(0.1)
Morphine Sulfate	1	(0.1)	3	(0.2)	4	(0.1)
Oxycodone Hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Hydromorphone	2	(0.1)	1	(0.1)	3	(0.1)
Caffeine; Codeine Phosphate; Meprobamate; Paracetamol	1	(0.1)	1	(0.1)	2	(0.1)
Codeine Phosphate; Paracetamol; Pentobarbital Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Hydromorphone Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Caffeine; Codeine; Meprobamate; Paracetamol	0		1	(0.1)	1	(0.0)
Vitamin B12 (Cyanocobalamin And Analogues), B03ba	25	(1.3)	25	(1.3)	50	(1.3)
Cyanocobalamin	21	(1.1)	20	(1.1)	41	(1.1)
Cyanocobalamin; Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	3	(0.2)	4	(0.1)
Cyanocobalamin-Tannin Complex	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate Dibasic; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Mononitrate	0		1	(0.1)	1	(0.0)
Cyanocobalamin; Lidocaine	1	(0.1)	0		1	(0.0)
Cyanocobalamin; Pyridoxine	0		1	(0.1)	1	(0.0)
Dexamethasone Sodium Phosphate; Hydroxocobalamin Acetate; Lidocaine Hydrochloride; Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Gabapentin, N03ax12	27	(1.4)	22	(1.2)	49	(1.3)
Gabapentin	27	(1.4)	22	(1.2)	49	(1.3)
Pyrazolones, N02bb	22	(1.2)	26	(1.4)	48	(1.3)
Metamizole Sodium	17	(0.9)	12	(0.6)	29	(0.8)
Metamizole	4	(0.2)	6	(0.3)	10	(0.3)
Aminophenazone	0		3	(0.2)	3	(0.1)
Metamizole Magnesium	0		3	(0.2)	3	(0.1)
Propyphenazone	1	(0.1)	2	(0.1)	3	(0.1)
Metamizole Sodium Monohydrate	0		1	(0.1)	1	(0.0)
Direct Factor Xa Inhibitors, B01af	28	(1.5)	19	(1.0)	47	(1.2)
Apixaban	12	(0.6)	11	(0.6)	23	(0.6)
Rivaroxaban	15	(0.8)	7	(0.4)	22	(0.6)
Edoxaban Tosilate	1	(0.1)	1	(0.1)	2	(0.1)
Insulins And Analogues For Injection, Fast-Acting, A10ab	19	(1.0)	27	(1.4)	46	(1.2)
Insulin Glulisine	18	(1.0)	27	(1.4)	45	(1.2)
Insulin Lispro Aabc	1	(0.1)	0		1	(0.0)
Unspecified Herbal And Traditional Medicine, V90	23	(1.2)	23	(1.2)	46	(1.2)
Traditional Medicine	10	(0.5)	7	(0.4)	17	(0.5)
Herbal Preparation	3	(0.2)	5	(0.3)	8	(0.2)
Unspecified Herbal	6	(0.3)	2	(0.1)	8	(0.2)
Unspecified Herbal And Traditional Medicine	0		3	(0.2)	3	(0.1)
Herbal Extract Nos	1	(0.1)	1	(0.1)	2	(0.1)
Aconitum Carmichaelii Root; Atractylodes Macrocephala, Rhizoma; Codonopsis Pilosula Root; Glycyrrhiza Uralensis Root With Rhizome; Zingiber Officinale Rhizome	0		1	(0.1)	1	(0.0)
Acorus Calamus Rhizome; Carum Carvi Fruit; Curcuma Longa Rhizome; Glycyrrhiza Spp. Root	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
With Rhizome; Minerals Nos; Musk; Myristica Fragrans; Nardostachys Jatamansi Root With Rhizome; Tronae; Zanthoxylum Spp.						
Akebia Quinata Stem; Alisma Orientale Rhizome; Angelica Sinensis Root; Bupleurum Chinense, Root; Gardenia Jasminoides Fruit; Gentiana Scabra Root; Glycyrrhiza Uralensis Root With Rhizome; Plantago Asiatica S	1	(0.1)	0		1	(0.0)
Alisma Orientale	1	(0.1)	0		1	(0.0)
Allium Sativum Bulb; Borneol; Crataegus Pinnatifida Fruit; Erigeron Breviscapus Herb; Ginkgo Biloba Leaf; Gynostemma Pentaphyllum Whole Plant; Panax Notoginseng Root; Salvia Miltiorrhiza Root	1	(0.1)	0		1	(0.0)
Angelica Sinensis Root; Codonopsis Pilosula Root; Glehnia Littoralis Root; Salvia Miltiorrhiza Root; Tinospora Sagittata Root Tuber	0		1	(0.1)	1	(0.0)
Arctium Lappa Fruit; Corydalis Bungeana Herb; Glycyrrhiza Uralensis Root With Rhizome; Lonicera Japonica Flower Bud; Platycodon Grandiflorus Root; Scrophularia Ningpoensis Root; Scutellaria Baicalensis Root	0		1	(0.1)	1	(0.0)
Astragalus Mongholicus Root; Crataegus Pinnatifida Fruit; Ligusticum Chuanxiong Rhizome; Ophiopogon Japonicus Root Tuber; Panax Ginseng Root; Salvia Miltiorrhiza Root; Schisandra Chinensis Fruit	1	(0.1)	0		1	(0.0)
Bacopa Monnieri Herb; Camellia Sinensis Leaf; Curcuma Longa Rhizome; Silybum Marianum Seed; Withania Somnifera Root	0		1	(0.1)	1	(0.0)
Bupleurum Chinense, Root; Codonopsis Pilosula Root; Glycyrrhiza Uralensis Root With Rhizome; Pinellia Ternata Rhizome; Scutellaria Baicalensis Root; Zingiber Officinale Rhizome; Ziziphus Jujuba Fruit	0		1	(0.1)	1	(0.0)
Chrysanthemum Indicum Flower; Ilex Asprella Root; Isatis Tinctoria Root; Lonicera Japonica Flower; Melicope Pteleifolia; Vitex Negundo	1	(0.1)	0		1	(0.0)
Chrysanthemum Indicum Inflorescence; Scutellaria Baicalensis Root; Taraxacum Mongolicum Herb; Viola Philippica Herb	0		1	(0.1)	1	(0.0)
Cinnamomum Verum Bark Oil; Citrus Limon Oil; Eucalyptus Radiata Oil; Rosmarinus Officinalis Oil; Syzygium Aromaticum Oil	1	(0.1)	0		1	(0.0)
Citrus Aurantium Fruit Peel; Crataegus Pinnatifida Fruit; Dioscorea Polystachya Rhizome; Hordeum Vulgare Sprout; Pseudostellaria Heterophylla Rhizome	1	(0.1)	0		1	(0.0)
Citrus Aurantium Fruit; Isodon Amethystoides; Panax Ginseng	1	(0.1)	0		1	(0.0)
Citrus Maxima Peel	0		1	(0.1)	1	(0.0)
Mentha Canadensis Oil	1	(0.1)	0		1	(0.0)
Phellodendron Spp.	1	(0.1)	0		1	(0.0)
Poria Cocos	0		1	(0.1)	1	(0.0)
Pueraria Spp. Root	0		1	(0.1)	1	(0.0)
Quercus Salicina Extract	0		1	(0.1)	1	(0.0)
Scutellaria Spp.	0		1	(0.1)	1	(0.0)
Sophora Flavescens Root; Trimethoprim	0		1	(0.1)	1	(0.0)
Traditional Chinese Medicine (Tcm) Decoction	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Opioids In Combination With Non-Opioid Analgesics, N02aj	27	(1.4)	18	(1.0)	45	(1.2)
Paracetamol; Tramadol Hydrochloride	6	(0.3)	4	(0.2)	10	(0.3)
Codeine Phosphate; Paracetamol	5	(0.3)	4	(0.2)	9	(0.2)
Hydrocodone Bitartrate; Paracetamol	6	(0.3)	2	(0.1)	8	(0.2)
Hydrocodone; Paracetamol	2	(0.1)	4	(0.2)	6	(0.2)
Codeine Phosphate; Ibuprofen; Paracetamol	3	(0.2)	0		3	(0.1)
Oxycodone Hydrochloride; Paracetamol	2	(0.1)	1	(0.1)	3	(0.1)
Codeine; Paracetamol	2	(0.1)	0		2	(0.1)
Ambroxol Hydrochloride; Caffeine; Chlorphenamine Maleate; Dihydrocodeine Phosphate; Ibuprofen; Methylephedrine Hydrochloride-Dl	1	(0.1)	0		1	(0.0)
Benfotiamine; Caffeine; Clemastine Fumarate; Dihydrocodeine Phosphate; Methylephedrine Hydrochloride-Dl; Noscapine; Paracetamol; Sulfogaiacol	0		1	(0.1)	1	(0.0)
Caffeine; Carbinoxamine Maleate; Dihydrocodeine Phosphate; Guaifenesin; Lysozyme Chloride; Methylephedrine Hydrochloride-Dl; Paracetamol; Riboflavin; Sulbutiamine	1	(0.1)	0		1	(0.0)
Caffeine; Chlorphenamine Maleate; Dihydrocodeine Phosphate; Glycyrrhiza Glabra Extract; Methylephedrine Hydrochloride-Dl; Paracetamol	0		1	(0.1)	1	(0.0)
Dexketoprofen Trometamol; Tramadol Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antivirals, J05ax	20	(1.1)	24	(1.3)	44	(1.2)
Umifenovir	10	(0.5)	15	(0.8)	25	(0.7)
Favipiravir	8	(0.4)	5	(0.3)	13	(0.3)
Inosine Pranobex	1	(0.1)	4	(0.2)	5	(0.1)
Bamlanivimab	1	(0.1)	1	(0.1)	2	(0.1)
Amenamevir	1	(0.1)	0		1	(0.0)
Tilorone	1	(0.1)	0		1	(0.0)
Other Lipid Modifying Agents, C10ax	20	(1.1)	23	(1.2)	43	(1.1)
Ezetimibe	13	(0.7)	12	(0.6)	25	(0.7)
Fish Oil	3	(0.2)	3	(0.2)	6	(0.2)
Omega-3-Acid Ethyl Ester	1	(0.1)	4	(0.2)	5	(0.1)
Evolocumab	2	(0.1)	1	(0.1)	3	(0.1)
Eicosapentaenoic Acid Ethyl Ester	0		2	(0.1)	2	(0.1)
Alirocumab	0		1	(0.1)	1	(0.0)
Dihydroquercetin	0		1	(0.1)	1	(0.0)
Linolenic Acid	1	(0.1)	0		1	(0.0)
Omega-3 Fatty Acids; Vitamin E Nos	0		1	(0.1)	1	(0.0)
Other Antidepressants, N06ax	20	(1.1)	22	(1.2)	42	(1.1)
Duloxetine	5	(0.3)	4	(0.2)	9	(0.2)
Duloxetine Hydrochloride	3	(0.2)	6	(0.3)	9	(0.2)
Bupropion Hydrochloride	1	(0.1)	5	(0.3)	6	(0.2)
Trazodone	1	(0.1)	5	(0.3)	6	(0.2)
Venlafaxine Hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Bupropion	3	(0.2)	0		3	(0.1)
Vortioxetine Hydrobromide	1	(0.1)	2	(0.1)	3	(0.1)
Mirtazapine	1	(0.1)	1	(0.1)	2	(0.1)
Tianeptine Sodium	1	(0.1)	1	(0.1)	2	(0.1)
Desvenlafaxine	1	(0.1)	0		1	(0.0)
Venlafaxine	1	(0.1)	0		1	(0.0)
Oxicams, M01ac	24	(1.3)	18	(1.0)	42	(1.1)
Meloxicam	19	(1.0)	11	(0.6)	30	(0.8)
Lornoxicam	3	(0.2)	4	(0.2)	7	(0.2)
Piroxicam	1	(0.1)	2	(0.1)	3	(0.1)
Tenoxicam	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Mucolytics, R05cb	25	(1.3)	15	(0.8)	40	(1.1)
L-Carbocisteine	7	(0.4)	5	(0.3)	12	(0.3)
Erdosteine	6	(0.3)	4	(0.2)	10	(0.3)
Carbocisteine	4	(0.2)	5	(0.3)	9	(0.2)
Bromhexine Hydrochloride	5	(0.3)	1	(0.1)	6	(0.2)
Bromhexine	2	(0.1)	1	(0.1)	3	(0.1)
Bromhexine Hydrochloride; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Benzodiazepine Derivatives, N05ba	16	(0.8)	23	(1.2)	39	(1.0)
Diazepam	2	(0.1)	14	(0.8)	16	(0.4)
Alprazolam	5	(0.3)	4	(0.2)	9	(0.2)
Lorazepam	6	(0.3)	3	(0.2)	9	(0.2)
Bromazepam	1	(0.1)	0		1	(0.0)
Clotiazepam	0		1	(0.1)	1	(0.0)
Etizolam	1	(0.1)	0		1	(0.0)
Medazepam	1	(0.1)	0		1	(0.0)
Phenazepam	0		1	(0.1)	1	(0.0)
Selective Beta-2-Adrenoreceptor Agonists, R03ac	25	(1.3)	14	(0.8)	39	(1.0)
Salbutamol	15	(0.8)	7	(0.4)	22	(0.6)
Salbutamol Sulfate	6	(0.3)	4	(0.2)	10	(0.3)
Ipratropium Bromide; Salbutamol Sulfate	3	(0.2)	0		3	(0.1)
Tulobuterol	1	(0.1)	2	(0.1)	3	(0.1)
Ipratropium; Salbutamol	1	(0.1)	1	(0.1)	2	(0.1)
Vilanterol Trifenatate	1	(0.1)	1	(0.1)	2	(0.1)
Indacaterol	1	(0.1)	0		1	(0.0)
Indacaterol Maleate	1	(0.1)	0		1	(0.0)
Ipratropium Bromide; Salbutamol	0		1	(0.1)	1	(0.0)
Vilanterol	0		1	(0.1)	1	(0.0)
Thiazides, Plain, C03aa	26	(1.4)	13	(0.7)	39	(1.0)
Hydrochlorothiazide	25	(1.3)	13	(0.7)	38	(1.0)
Trichlormethiazide	1	(0.1)	0		1	(0.0)
Selective Serotonin Reuptake Inhibitors, N06ab	22	(1.2)	16	(0.8)	38	(1.0)
Escitalopram	6	(0.3)	2	(0.1)	8	(0.2)
Sertraline	3	(0.2)	5	(0.3)	8	(0.2)
Escitalopram Oxalate	4	(0.2)	1	(0.1)	5	(0.1)
Sertraline Hydrochloride	3	(0.2)	2	(0.1)	5	(0.1)
Citalopram	3	(0.2)	1	(0.1)	4	(0.1)
Citalopram Hydrobromide	2	(0.1)	1	(0.1)	3	(0.1)
Paroxetine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Fluoxetine Hydrochloride	0		1	(0.1)	1	(0.0)
Fluvoxamine Maleate	0		1	(0.1)	1	(0.0)
Paroxetine	0		1	(0.1)	1	(0.0)
Tetracyclines, J01aa	22	(1.2)	15	(0.8)	37	(1.0)
Doxycycline	19	(1.0)	12	(0.6)	31	(0.8)
Doxycycline Hyclate	2	(0.1)	2	(0.1)	4	(0.1)
Minocycline Hydrochloride	2	(0.1)	0		2	(0.1)
Doxycycline Hydrochloride	1	(0.1)	0		1	(0.0)
Doxycycline Monohydrate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Potassium, A12ba	19	(1.0)	17	(0.9)	36	(1.0)
Potassium Chloride	13	(0.7)	15	(0.8)	28	(0.8)
Potassium Chloride; Sodium Chloride	2	(0.1)	0		2	(0.1)
Calcium Chloride Dihydrate; Glucose; Potassium Chloride; Sodium Acetate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Calcium Chloride Dihydrate; Glucose; Potassium Chloride; Sodium Lactate	1	(0.1)	0		1	(0.0)
Calcium Chloride Dihydrate; Magnesium Chloride Hexahydrate; Potassium Chloride; Sodium Acetate Trihydrate; Sodium Chloride; Sodium Citrate Dihydrate	1	(0.1)	0		1	(0.0)
Calcium Chloride; Potassium Chloride; Sodium Acetate; Sodium Chloride	1	(0.1)	0		1	(0.0)
Glucose; Potassium Chloride; Sodium Chloride; Sodium Citrate	1	(0.1)	0		1	(0.0)
Macrogol 4000; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate	1	(0.1)	0		1	(0.0)
Macrogol 4000; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate Anhydrous	1	(0.1)	0		1	(0.0)
Magnesium Sulfate; Potassium Chloride	0		1	(0.1)	1	(0.0)
Aminoalkyl Ethers, R06aa	19	(1.0)	16	(0.8)	35	(0.9)
Diphenhydramine Hydrochloride	12	(0.6)	6	(0.3)	18	(0.5)
Diphenhydramine	6	(0.3)	7	(0.4)	13	(0.3)
Piprinhydrinate	1	(0.1)	1	(0.1)	2	(0.1)
Diphenhydramine Hydrochloride; Naphazoline Hydrochloride	0		1	(0.1)	1	(0.0)
Diphenhydramine Salicylate	0		1	(0.1)	1	(0.0)
Diphenylpyraline Hydrochloride	0		1	(0.1)	1	(0.0)
Expectorants, R05ca	17	(0.9)	17	(0.9)	34	(0.9)
Guaifenesin	15	(0.8)	14	(0.8)	29	(0.8)
Guaifenesin; Pseudoephedrine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Bromhexine Hydrochloride; Guaifenesin; Menthol; Terbutaline Sulfate	0		1	(0.1)	1	(0.0)
Bromhexine Hydrochloride; Guaifenesin; Salbutamol Sulfate	0		1	(0.1)	1	(0.0)
Drosera Rotundifolia Extract; Ephedrine Hydrochloride; Saponin; Thymus Vulgaris Oil	1	(0.1)	0		1	(0.0)
Expectorants	1	(0.1)	0		1	(0.0)
Iron Bivalent, Oral Preparations, B03aa	16	(0.8)	17	(0.9)	33	(0.9)
Ferrous Glycine Sulfate	6	(0.3)	7	(0.4)	13	(0.3)
Ferrous Sulfate	5	(0.3)	8	(0.4)	13	(0.3)
Ferrous Fumarate	4	(0.2)	1	(0.1)	5	(0.1)
Ferrous Sodium Citrate	0		3	(0.2)	3	(0.1)
Ferrous Ascorbate	1	(0.1)	0		1	(0.0)
Other Cough Suppressants, R05db	18	(1.0)	15	(0.8)	33	(0.9)
Benzonatate	11	(0.6)	8	(0.4)	19	(0.5)
Cloperastine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Other Cough Suppressants	2	(0.1)	0		2	(0.1)
Oxolamine Phosphate	0		2	(0.1)	2	(0.1)
Benproperine	0		1	(0.1)	1	(0.0)
Butamirate Citrate	0		1	(0.1)	1	(0.0)
Clofedanol Hydrochloride	1	(0.1)	0		1	(0.0)
Dropropizine	0		1	(0.1)	1	(0.0)
Levodropropizine	1	(0.1)	0		1	(0.0)
Oxolamine Citrate	0		1	(0.1)	1	(0.0)
Pentoxyverine	1	(0.1)	0		1	(0.0)
Tipepidine Hibenzate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Benzodiazepine Derivatives, N05cd	16	(0.8)	16	(0.8)	32	(0.8)
Midazolam	3	(0.2)	10	(0.5)	13	(0.3)
Midazolam Hydrochloride	4	(0.2)	1	(0.1)	5	(0.1)
Temazepam	3	(0.2)	1	(0.1)	4	(0.1)
Brotizolam	2	(0.1)	1	(0.1)	3	(0.1)
Nitrazepam	1	(0.1)	2	(0.1)	3	(0.1)
Estazolam	1	(0.1)	1	(0.1)	2	(0.1)
Flurazepam Hydrochloride	1	(0.1)	0		1	(0.0)
Loprazolam Mesilate	1	(0.1)	0		1	(0.0)
Contact Laxatives, A06ab	16	(0.8)	16	(0.8)	32	(0.8)
Sennoside A+B	4	(0.2)	4	(0.2)	8	(0.2)
Bisacodyl	2	(0.1)	5	(0.3)	7	(0.2)
Sennoside A+B Calcium	2	(0.1)	3	(0.2)	5	(0.1)
Citric Acid; Magnesium Oxide; Sodium Picosulfate	2	(0.1)	2	(0.1)	4	(0.1)
Docusate; Senna Alexandrina	1	(0.1)	2	(0.1)	3	(0.1)
Contact Laxatives	1	(0.1)	1	(0.1)	2	(0.1)
Docusate Sodium; Sennoside A+B	2	(0.1)	0		2	(0.1)
Sodium Picosulfate	1	(0.1)	1	(0.1)	2	(0.1)
Bisacodyl; Docusate Sodium; Sennoside A+B	0		1	(0.1)	1	(0.0)
Docusate Sodium; Senna Alexandrina	1	(0.1)	0		1	(0.0)
Phenolphthalein	1	(0.1)	0		1	(0.0)
Sodium Picosulfate Monohydrate	0		1	(0.1)	1	(0.0)
Serotonin (5ht3) Antagonists, A04aa	17	(0.9)	15	(0.8)	32	(0.8)
Ondansetron	14	(0.7)	14	(0.8)	28	(0.8)
Ondansetron Hydrochloride	3	(0.2)	1	(0.1)	4	(0.1)
Granisetron	1	(0.1)	0		1	(0.0)
Palonosetron	1	(0.1)	0		1	(0.0)
Alpha And Beta Blocking Agents, C07ag	13	(0.7)	18	(1.0)	31	(0.8)
Carvedilol	13	(0.7)	16	(0.8)	29	(0.8)
Labetalol	0		3	(0.2)	3	(0.1)
Second-Generation Cephalosporins, J01dc	20	(1.1)	10	(0.5)	30	(0.8)
Cefuroxime Axetil	9	(0.5)	4	(0.2)	13	(0.3)
Cefaclor	8	(0.4)	3	(0.2)	11	(0.3)
Cefprozil	2	(0.1)	1	(0.1)	3	(0.1)
Cefmetazole Sodium	0		1	(0.1)	1	(0.0)
Cefoxitin	0		1	(0.1)	1	(0.0)
Cefprozil Monohydrate	1	(0.1)	0		1	(0.0)
Aldosterone Antagonists, C03da	16	(0.8)	13	(0.7)	29	(0.8)
Spironolactone	13	(0.7)	9	(0.5)	22	(0.6)
Eplerenone	3	(0.2)	1	(0.1)	4	(0.1)
Esaxerenone	0		2	(0.1)	2	(0.1)
Potassium Canrenoate	0		1	(0.1)	1	(0.0)
Alpha-Adrenoreceptor Antagonists, G04ca	15	(0.8)	14	(0.8)	29	(0.8)
Tamsulosin	7	(0.4)	4	(0.2)	11	(0.3)
Tamsulosin Hydrochloride	6	(0.3)	4	(0.2)	10	(0.3)
Silodosin	3	(0.2)	2	(0.1)	5	(0.1)
Terazosin	0		2	(0.1)	2	(0.1)
Alfuzosin Hydrochloride	0		1	(0.1)	1	(0.0)
Terazosin Hydrochloride	0		1	(0.1)	1	(0.0)
Leukotriene Receptor Antagonists, R03dc	12	(0.6)	15	(0.8)	27	(0.7)
Montelukast	6	(0.3)	5	(0.3)	11	(0.3)
Montelukast Sodium	4	(0.2)	7	(0.4)	11	(0.3)
Levocetirizine Dihydrochloride; Montelukast Sodium	2	(0.1)	2	(0.1)	4	(0.1)
Levocetirizine; Montelukast	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Pneumococcal Vaccines, J07al	14	(0.7)	13	(0.7)	27	(0.7)
Pneumococcal Vaccine	5	(0.3)	5	(0.3)	10	(0.3)
Pneumococcal Vaccine Polysacch 23v	6	(0.3)	4	(0.2)	10	(0.3)
Pneumococcal Vaccine Conj 7v (Crm197)	1	(0.1)	2	(0.1)	3	(0.1)
Pneumococcal Vaccine Conj 13v (Crm197)	1	(0.1)	1	(0.1)	2	(0.1)
Pneumococcal Vaccine 13v	1	(0.1)	0		1	(0.0)
Pneumococcal Vaccine Polyv	0		1	(0.1)	1	(0.0)
Antidiarrheal Microorganisms, A07fa	14	(0.7)	11	(0.6)	25	(0.7)
Bifidobacterium Nos	4	(0.2)	1	(0.1)	5	(0.1)
Saccharomyces Boulardii	5	(0.3)	0		5	(0.1)
Bacillus Mesentericus; Clostridium Butyricum; Enterococcus Faecalis	2	(0.1)	1	(0.1)	3	(0.1)
Antibiotics-Resistant Lactic Acid Bacteriae	1	(0.1)	1	(0.1)	2	(0.1)
Enterococcus Faecalis	1	(0.1)	1	(0.1)	2	(0.1)
Lactobacillus Helveticus; Lactobacillus Rhamnosus	1	(0.1)	1	(0.1)	2	(0.1)
Bacillus Lichenformis	0		1	(0.1)	1	(0.0)
Bifidobacterium Bifidum	1	(0.1)	0		1	(0.0)
Bifidobacterium Breve; Bifidobacterium Infantis; Bifidobacterium Longum; Lactobacillus Acidophilus; Lactobacillus Bulgaricus; Lactobacillus Paracasei; Lactobacillus Plantarum; Streptococcus Thermophilus	0		1	(0.1)	1	(0.0)
Bifidobacterium Lactis	0		1	(0.1)	1	(0.0)
Bifidobacterium Lactis; Fructooligosaccharides; Inulin; Lactobacillus Acidophilus; Lactobacillus Casei; Lactobacillus Plantarum; Lactobacillus Salivarius	0		1	(0.1)	1	(0.0)
Bifidobacterium Longum; Enterococcus Faecalis; Lactobacillus Acidophilus	1	(0.1)	0		1	(0.0)
Bifidobacterium Longum; Enterococcus Faecium	0		1	(0.1)	1	(0.0)
Enterococcus Faecalis; Escherichia Coli; Lactobacillus Acidophilus; Lactobacillus Helveticus	0		1	(0.1)	1	(0.0)
H2-Receptor Antagonists, A02ba	18	(1.0)	7	(0.4)	25	(0.7)
Famotidine	13	(0.7)	7	(0.4)	20	(0.5)
Cimetidine	1	(0.1)	0		1	(0.0)
Domperidone; Ranitidine	1	(0.1)	0		1	(0.0)
Lafutidine	1	(0.1)	0		1	(0.0)
Ondansetron Hydrochloride; Ranitidine Hydrochloride	1	(0.1)	0		1	(0.0)
Ranitidine	1	(0.1)	0		1	(0.0)
Magnesium Compounds, A02aa	7	(0.4)	18	(1.0)	25	(0.7)
Magnesium Oxide	6	(0.3)	15	(0.8)	21	(0.6)
Magnesium Hydroxide	1	(0.1)	3	(0.2)	4	(0.1)
Sulfonamides, Plain, C03ba	14	(0.7)	11	(0.6)	25	(0.7)
Indapamide	10	(0.5)	9	(0.5)	19	(0.5)
Chlortalidone	4	(0.2)	2	(0.1)	6	(0.2)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Sympathomimetics, R01ba	11	(0.6)	14	(0.8)	25	(0.7)
Pseudoephedrine Hydrochloride	2	(0.1)	9	(0.5)	11	(0.3)
Pseudoephedrine	4	(0.2)	3	(0.2)	7	(0.2)
Pseudoephedrine Hydrochloride; Triprolidine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Atropa Belladonna Extract; Caffeine; Carbinoxamine Maleate; Lysozyme Chloride; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Atropa Belladonna Total Alkaloid Extract; Caffeine; Dipotassium Glycyrrhizate; Mequitazine; Methylephedrine Hydrochloride-Dl; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Diphenhydramine Hydrochloride; Pseudoephedrine Hydrochloride	1	(0.1)	0		1	(0.0)
Loratadine; Pseudoephedrine Sulfate	1	(0.1)	0		1	(0.0)
Corticosteroids, R01ad	13	(0.7)	11	(0.6)	24	(0.6)
Fluticasone Propionate	13	(0.7)	9	(0.5)	22	(0.6)
Azelastine Hydrochloride; Fluticasone Propionate	0		1	(0.1)	1	(0.0)
Dexamethasone Cipecilate	0		1	(0.1)	1	(0.0)
Preparations Inhibiting Uric Acid Production, M04aa	14	(0.7)	10	(0.5)	24	(0.6)
Allopurinol	11	(0.6)	8	(0.4)	19	(0.5)
Febuxostat	3	(0.2)	2	(0.1)	5	(0.1)
Drugs For Urinary Frequency And Incontinence, G04bd	12	(0.6)	11	(0.6)	23	(0.6)
Mirabegron	6	(0.3)	3	(0.2)	9	(0.2)
Oxybutynin	1	(0.1)	2	(0.1)	3	(0.1)
Tolterodine L-Tartrate	2	(0.1)	1	(0.1)	3	(0.1)
Vibegron	1	(0.1)	2	(0.1)	3	(0.1)
Oxybutynin Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Propiverine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Fesoterodine	1	(0.1)	0		1	(0.0)
Fesoterodine Fumarate	0		1	(0.1)	1	(0.0)
Flavoxate Hydrochloride	1	(0.1)	0		1	(0.0)
Solifenacin Succinate	0		1	(0.1)	1	(0.0)
Tolterodine	0		1	(0.1)	1	(0.0)
Non-Selective Monoamine Reuptake Inhibitors, N06aa	11	(0.6)	12	(0.6)	23	(0.6)
Amitriptyline	7	(0.4)	5	(0.3)	12	(0.3)
Amitriptyline Hydrochloride	2	(0.1)	4	(0.2)	6	(0.2)
Nortriptyline	2	(0.1)	1	(0.1)	3	(0.1)
Nortriptyline Hydrochloride	0		1	(0.1)	1	(0.0)
Opipramol Hydrochloride	0		1	(0.1)	1	(0.0)
Nucleosides And Nucleotides Excl. Reverse Transcriptase Inhibitors, J05ab	13	(0.7)	10	(0.5)	23	(0.6)
Valaciclovir Hydrochloride	6	(0.3)	6	(0.3)	12	(0.3)
Valaciclovir	4	(0.2)	3	(0.2)	7	(0.2)
Remdesivir	3	(0.2)	2	(0.1)	5	(0.1)
Antipropulsives, A07da	15	(0.8)	7	(0.4)	22	(0.6)
Loperamide Hydrochloride	7	(0.4)	4	(0.2)	11	(0.3)
Loperamide	7	(0.4)	3	(0.2)	10	(0.3)
Diphenoxylate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Calcium, A12aa	10	(0.5)	12	(0.6)	22	(0.6)
Calcium Carbonate	3	(0.2)	6	(0.3)	9	(0.2)
Calcium	3	(0.2)	5	(0.3)	8	(0.2)
Calcium Citrate	3	(0.2)	2	(0.1)	5	(0.1)
Calcium Carbonate; Calcium Lactate Gluconate	1	(0.1)	0		1	(0.0)
Nitrofuran Derivatives, J01xe	9	(0.5)	13	(0.7)	22	(0.6)
Nitrofurantoin	7	(0.4)	11	(0.6)	18	(0.5)
Furazidin	1	(0.1)	2	(0.1)	3	(0.1)
Nitrofurantoin Monohydrate	1	(0.1)	0		1	(0.0)
Thiazolidinediones, A10bg	10	(0.5)	12	(0.6)	22	(0.6)
Pioglitazone	6	(0.3)	9	(0.5)	15	(0.4)
Pioglitazone Hydrochloride	4	(0.2)	2	(0.1)	6	(0.2)
Lobeglitazone	0		1	(0.1)	1	(0.0)
Antivertigo Preparations, N07ca	8	(0.4)	13	(0.7)	21	(0.6)
Betahistine Hydrochloride	3	(0.2)	6	(0.3)	9	(0.2)
Betahistine	4	(0.2)	4	(0.2)	8	(0.2)
Betahistine Mesilate	2	(0.1)	2	(0.1)	4	(0.1)
Cinnarizine	1	(0.1)	1	(0.1)	2	(0.1)
Opium Derivatives And Expectorants, R05fa	8	(0.4)	13	(0.7)	21	(0.6)
Dextromethorphan Hydrobromide; Guaifenesin	2	(0.1)	7	(0.4)	9	(0.2)
Ammonia; Benzoic Acid; Camphor; Glycerol; Glycyrrhiza Spp. Root With Rhizome; Guaifenesin; Illicium Verum Oil; Papaver Somniferum Tincture	1	(0.1)	2	(0.1)	3	(0.1)
Dextromethorphan; Guaifenesin	1	(0.1)	1	(0.1)	2	(0.1)
Ammonium Chloride; Aster Tataricus Root With Rhizome; Citrus Aurantium Epicarp; Citrus Aurantium Fruit Peel; Citrus Aurantium Unripe Fruit; Glycyrrhiza Spp. Root With Rhizome; Mentha Canadensis Herb Oil; Pap	0		1	(0.1)	1	(0.0)
Ammonium Chloride; Bromhexine; Dextromethorphan; Menthol	1	(0.1)	0		1	(0.0)
Ammonium Chloride; Chlorphenamine Maleate; Dextromethorphan Hydrobromide; Guaifenesin	0		1	(0.1)	1	(0.0)
Antimony Potassium Tartrate; Papaver Somniferum Tincture; Terpin	1	(0.1)	0		1	(0.0)
Codeine Phosphate; Guaifenesin	0		1	(0.1)	1	(0.0)
Codeine; Guaifenesin	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin; Phenylephrine	1	(0.1)	0		1	(0.0)
Dextromethorphan Hydrobromide; Guaifenesin; Pseudoephedrine Hydrochloride	0		1	(0.1)	1	(0.0)
Dextromethorphan; Guaifenesin; Phenylephrine	1	(0.1)	0		1	(0.0)
Phenylpiperidine Derivatives, N02ab	8	(0.4)	13	(0.7)	21	(0.6)
Fentanyl	6	(0.3)	6	(0.3)	12	(0.3)
Pethidine Hydrochloride	2	(0.1)	3	(0.2)	5	(0.1)
Fentanyl Citrate	0		2	(0.1)	2	(0.1)
Pethidine	0		2	(0.1)	2	(0.1)
Propulsives, A03fa	6	(0.3)	15	(0.8)	21	(0.6)
Domperidone	4	(0.2)	7	(0.4)	11	(0.3)
Mosapride Citrate	1	(0.1)	5	(0.3)	6	(0.2)
Cinitapride	0		3	(0.2)	3	(0.1)
Domperidone Maleate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Thyroid Hormones, H03aa	16	(0.8)	5	(0.3)	21	(0.6)
Levothyroxine Sodium	9	(0.5)	3	(0.2)	12	(0.3)
Levothyroxine	7	(0.4)	2	(0.1)	9	(0.2)
Liothyronine	1	(0.1)	0		1	(0.0)
Vitamin B1, Plain, A11da	13	(0.7)	8	(0.4)	21	(0.6)
Thiamine Hydrochloride	5	(0.3)	4	(0.2)	9	(0.2)
Thiamine	4	(0.2)	3	(0.2)	7	(0.2)
Benfotiamine	3	(0.2)	2	(0.1)	5	(0.1)
Fursultiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Belladonna Alkaloids, Semisynthetic, Quaternary Ammonium Compounds, A03bb	9	(0.5)	11	(0.6)	20	(0.5)
Hyoscine Butylbromide	9	(0.5)	10	(0.5)	19	(0.5)
Cimetropium Bromide	0		1	(0.1)	1	(0.0)
Organic Nitrates, C01da	9	(0.5)	11	(0.6)	20	(0.5)
Glyceryl Trinitrate	6	(0.3)	10	(0.5)	16	(0.4)
Isosorbide Mononitrate	3	(0.2)	1	(0.1)	4	(0.1)
Isosorbide Dinitrate	0		2	(0.1)	2	(0.1)
Osmotically Acting Laxatives, A06ad	8	(0.4)	12	(0.6)	20	(0.5)
Lactulose	4	(0.2)	3	(0.2)	7	(0.2)
Macrogol 3350	4	(0.2)	3	(0.2)	7	(0.2)
Ascorbic Acid; Macrogol 3350; Potassium Chloride; Sodium Ascorbate; Sodium Chloride; Sodium Sulfate	1	(0.1)	3	(0.2)	4	(0.1)
Ascorbic Acid; Macrogol 3350; Potassium Chloride; Sodium Ascorbate; Sodium Chloride; Sodium Sulfate Anhydrous	0		1	(0.1)	1	(0.0)
Macrogol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Macrogol 3350; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Sulfate	0		1	(0.1)	1	(0.0)
Tranexamic Acid, B02aa02	10	(0.5)	10	(0.5)	20	(0.5)
Tranexamic Acid	10	(0.5)	9	(0.5)	19	(0.5)
Glycyrrhiza Spp.; Pyridoxine Hydrochloride; Riboflavin; Sodium Ascorbate; Tranexamic Acid	0		1	(0.1)	1	(0.0)
Amides, N01bb	12	(0.6)	7	(0.4)	19	(0.5)
Ropivacaine	4	(0.2)	1	(0.1)	5	(0.1)
Epinephrine; Lidocaine	0		3	(0.2)	3	(0.1)
Mepivacaine Hydrochloride	3	(0.2)	0		3	(0.1)
Trimecaine Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Mepivacaine	2	(0.1)	0		2	(0.1)
Articaine Hydrochloride; Epinephrine Bitartrate	0		1	(0.1)	1	(0.0)
Articaine; Epinephrine	1	(0.1)	0		1	(0.0)
Epinephrine Bitartrate; Lidocaine Hydrochloride	1	(0.1)	0		1	(0.0)
Ropivacaine Hydrochloride	1	(0.1)	0		1	(0.0)
Carbohydrates, V06dc	10	(0.5)	9	(0.5)	19	(0.5)
Glucose	8	(0.4)	8	(0.4)	16	(0.4)
Glucose; Sodium Chloride	3	(0.2)	0		3	(0.1)
Electrolytes Nos; Glucose	0		1	(0.1)	1	(0.0)
Varicella Zoster Vaccines, J07bk	10	(0.5)	8	(0.4)	18	(0.5)
Varicella Zoster Vaccine Rge (Cho)	8	(0.4)	7	(0.4)	15	(0.4)
Varicella Zoster Vaccine Live (Oka/Merck)	2	(0.1)	0		2	(0.1)
Varicella Zoster Vaccine Live (Oka)	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Adrenergics In Combination With Corticosteroids Or Other Drugs, Excl. Anticholinergics, R03ak	9	(0.5)	8	(0.4)	17	(0.5)
Budesonide; Formoterol Fumarate	3	(0.2)	3	(0.2)	6	(0.2)
Beclometasone Dipropionate; Formoterol Fumarate	2	(0.1)	1	(0.1)	3	(0.1)
Fluticasone Propionate; Salmeterol Xinafoate	1	(0.1)	2	(0.1)	3	(0.1)
Fluticasone; Salmeterol	1	(0.1)	1	(0.1)	2	(0.1)
Formoterol Fumarate; Mometasone Furoate	2	(0.1)	0		2	(0.1)
Fluticasone Furoate; Vilanterol Trifenatate	0		1	(0.1)	1	(0.0)
Alpha-Adrenoreceptor Antagonists, C02ca	10	(0.5)	7	(0.4)	17	(0.5)
Doxazosin	6	(0.3)	2	(0.1)	8	(0.2)
Doxazosin Mesilate	2	(0.1)	4	(0.2)	6	(0.2)
Urapidil	2	(0.1)	1	(0.1)	3	(0.1)
Combinations Of Sulfonamides And Trimethoprim, Incl. Derivatives, J01ee	6	(0.3)	11	(0.6)	17	(0.5)
Sulfamethoxazole; Trimethoprim	6	(0.3)	11	(0.6)	17	(0.5)
Other Ophthalmologicals, S01xa	10	(0.5)	7	(0.4)	17	(0.5)
Pirenoxine	3	(0.2)	0		3	(0.1)
Paraffin; Paraffin, Liquid; Retinol Palmitate; White Soft Paraffin; Wool Fat	2	(0.1)	0		2	(0.1)
Artificial Tears [Umbrella Term]	1	(0.1)	0		1	(0.0)
Azapentacene Polysulfonate Sodium	1	(0.1)	0		1	(0.0)
Calcium Chloride Dihydrate; Glucose; Glutathione; Magnesium Chloride; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride; Sodium Phosphate	0		1	(0.1)	1	(0.0)
Carmellose; Glycerol	0		1	(0.1)	1	(0.0)
Citicoline Sodium; Cyanocobalamin; Hyaluronic Acid; Sodium Chloride; Sodium Phosphate Dibasic Dodecahydrate; Sodium Phosphate Monobasic (Monohydrate)	0		1	(0.1)	1	(0.0)
Diquafosol Tetrasodium	0		1	(0.1)	1	(0.0)
Docosahexaenoic Acid; Eicosapentaenoic Acid; Xantofyl; Zeaxanthin	1	(0.1)	0		1	(0.0)
Hyaluronate Sodium; Macrogol 400; Propylene Glycol	0		1	(0.1)	1	(0.0)
Hyaluronate Sodium; Trehalose	0		1	(0.1)	1	(0.0)
Iodolecithin	1	(0.1)	0		1	(0.0)
Macrogol 400; Propylene Glycol	0		1	(0.1)	1	(0.0)
Trehalose	1	(0.1)	0		1	(0.0)
Various Alimentary Tract And Metabolism Products, A16ax	8	(0.4)	9	(0.5)	17	(0.5)
Thioctic Acid	8	(0.4)	8	(0.4)	16	(0.4)
Thioctic Acid Sodium	0		2	(0.1)	2	(0.1)
Diphenylmethane Derivatives, N05bb	6	(0.3)	10	(0.5)	16	(0.4)
Hydroxyzine Hydrochloride	3	(0.2)	6	(0.3)	9	(0.2)
Hydroxyzine	3	(0.2)	3	(0.2)	6	(0.2)
Hydroxyzine Embonate	0		1	(0.1)	1	(0.0)
Magnesium, A12cc	8	(0.4)	8	(0.4)	16	(0.4)
Magnesium	4	(0.2)	7	(0.4)	11	(0.3)
Magnesium Aspartate	1	(0.1)	0		1	(0.0)
Magnesium Aspartate Hydrochloride	1	(0.1)	0		1	(0.0)
Magnesium Gluconate	0		1	(0.1)	1	(0.0)
Magnesium Glycinate	1	(0.1)	0		1	(0.0)
Magnesium Pidolate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Antibacterials, J01xx	9	(0.5)	7	(0.4)	16	(0.4)
Fosfomycin	5	(0.3)	2	(0.1)	7	(0.2)
Linezolid	1	(0.1)	3	(0.2)	4	(0.1)
Fosfomycin Trometamol	1	(0.1)	2	(0.1)	3	(0.1)
D-Mannose	1	(0.1)	0		1	(0.0)
Methenamine	1	(0.1)	0		1	(0.0)
Methenamine Anhydromethylenecitrate	1	(0.1)	0		1	(0.0)
Other Blood Glucose Lowering Drugs, Excl. Insulins, A10bx	7	(0.4)	9	(0.5)	16	(0.4)
Repaglinide	5	(0.3)	6	(0.3)	11	(0.3)
Mitiglinide Calcium	1	(0.1)	1	(0.1)	2	(0.1)
Nateglinide	0		2	(0.1)	2	(0.1)
Bromocriptine Mesilate	1	(0.1)	0		1	(0.0)
Alpha Glucosidase Inhibitors, A10bf	7	(0.4)	8	(0.4)	15	(0.4)
Acarbose	5	(0.3)	6	(0.3)	11	(0.3)
Voglibose	1	(0.1)	2	(0.1)	3	(0.1)
Miglitol	2	(0.1)	0		2	(0.1)
Carbamic Acid Esters, M03ba	8	(0.4)	7	(0.4)	15	(0.4)
Methocarbamol	6	(0.3)	7	(0.4)	13	(0.3)
Carisoprodol	2	(0.1)	0		2	(0.1)
Acetylsalicylic Acid; Codeine Phosphate; Methocarbamol	0		1	(0.1)	1	(0.0)
Acetylsalicylic Acid; Methocarbamol	0		1	(0.1)	1	(0.0)
Solutions Affecting The Electrolyte Balance, B05bb	8	(0.4)	7	(0.4)	15	(0.4)
Calcium Chloride Dihydrate; Potassium Chloride; Sodium Chloride; Sodium Lactate	3	(0.2)	1	(0.1)	4	(0.1)
Gluconate Sodium; Magnesium Chloride Hexahydrate; Potassium Chloride; Sodium Acetate Trihydrate; Sodium Chloride	2	(0.1)	2	(0.1)	4	(0.1)
Calcium Chloride; Potassium Chloride; Sodium Lactate	0		3	(0.2)	3	(0.1)
Glucose; Sodium Chloride; Sodium Lactate	2	(0.1)	0		2	(0.1)
Calcium Chloride; Glucose Monohydrate; Potassium Chloride; Sodium Chloride; Sodium Lactate	1	(0.1)	0		1	(0.0)
Calcium Chloride; Potassium Chloride; Sodium Chloride; Sodium Lactate	0		1	(0.1)	1	(0.0)
Glucose; Magnesium Chloride Hexahydrate; Potassium Chloride; Potassium Phosphate Monobasic; Sodium Acetate Trihydrate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Glucose; Potassium Chloride	1	(0.1)	0		1	(0.0)
Potassium Chloride; Sodium Chloride; Sodium Lactate	1	(0.1)	0		1	(0.0)
Antiarrhythmics, Class Iii, C01bd	6	(0.3)	8	(0.4)	14	(0.4)
Amiodarone	3	(0.2)	6	(0.3)	9	(0.2)
Amiodarone Hydrochloride	3	(0.2)	2	(0.1)	5	(0.1)
Benzodiazepine Related Drugs, N05cf	6	(0.3)	8	(0.4)	14	(0.4)
Zolpidem	3	(0.2)	3	(0.2)	6	(0.2)
Zolpidem Tartrate	2	(0.1)	3	(0.2)	5	(0.1)
Zopiclone	1	(0.1)	1	(0.1)	2	(0.1)
Eszopiclone	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Imidazoline Receptor Agonists, C02ac	7	(0.4)	7	(0.4)	14	(0.4)
Clonidine	3	(0.2)	2	(0.1)	5	(0.1)
Moxonidine	2	(0.1)	3	(0.2)	5	(0.1)
Clonidine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Rilmenidine	0		1	(0.1)	1	(0.0)
Rilmenidine Phosphate	1	(0.1)	0		1	(0.0)
Other Drugs For Functional Gastrointestinal Disorders, A03ax	5	(0.3)	9	(0.5)	14	(0.4)
Simeticone	2	(0.1)	4	(0.2)	6	(0.2)
Pinaverium Bromide	0		2	(0.1)	2	(0.1)
Alverine Citrate; Simeticone	0		1	(0.1)	1	(0.0)
Atractylodes Macrocephala, Rhizoma; Glycyrrhiza Spp. Root With Rhizome; Levoglutamide; Panax Ginseng Root With Rhizome; Poria Cocos Sclerotium	1	(0.1)	0		1	(0.0)
Dimeticone; Guaiazulene	1	(0.1)	0		1	(0.0)
Fenoverine	1	(0.1)	0		1	(0.0)
Flopropione	0		1	(0.1)	1	(0.0)
Sodium Butyrate	0		1	(0.1)	1	(0.0)
Watersoluble, Nephrotropic, Low Osmolar X-Ray Contrast Media, V08ab	10	(0.5)	4	(0.2)	14	(0.4)
Iohexol	5	(0.3)	2	(0.1)	7	(0.2)
Iopamidol	4	(0.2)	1	(0.1)	5	(0.1)
Iodixanol	1	(0.1)	0		1	(0.0)
Iopromide	0		1	(0.1)	1	(0.0)
Ioversol	0		1	(0.1)	1	(0.0)
Corticosteroids And Antiinfectives In Combination, S01ca	7	(0.4)	6	(0.3)	13	(0.3)
Dexamethasone; Tobramycin	5	(0.3)	2	(0.1)	7	(0.2)
Dexamethasone; Neomycin Sulfate; Polymyxin B Sulfate	2	(0.1)	2	(0.1)	4	(0.1)
Betamethasone Sodium Phosphate; Chloramphenicol; Colistimethate Sodium; Rolitetracycline	1	(0.1)	1	(0.1)	2	(0.1)
Dexamethasone Sodium Phosphate; Levofloxacin Hemihydrate	0		1	(0.1)	1	(0.0)
Other Cardiac Preparations, C01eb	7	(0.4)	6	(0.3)	13	(0.3)
Ranolazine	1	(0.1)	2	(0.1)	3	(0.1)
Trimetazidine Hydrochloride	0		3	(0.2)	3	(0.1)
Ivabradine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Trimetazidine	2	(0.1)	0		2	(0.1)
Ubidecarenone	2	(0.1)	0		2	(0.1)
Adenosine Triphosphate, Disodium Salt	1	(0.1)	0		1	(0.0)
Ivabradine	0		1	(0.1)	1	(0.0)
Ivabradine Oxalate	0		1	(0.1)	1	(0.0)
Other Psychostimulants And Nootropics, N06bx	5	(0.3)	8	(0.4)	13	(0.3)
Piracetam	3	(0.2)	2	(0.1)	5	(0.1)
Vinpocetine	1	(0.1)	4	(0.2)	5	(0.1)
Inosine; Nicotinamide; Riboflavin; Succinic Acid	1	(0.1)	3	(0.2)	4	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamins, Other Combinations, A11jc	4	(0.2)	9	(0.5)	13	(0.3)
Vitamins, Other Combinations	2	(0.1)	3	(0.2)	5	(0.1)
Colecalciferol; Folic Acid; Mecobalamin; Pyridoxine Hydrochloride; Thioctic Acid	0		3	(0.2)	3	(0.1)
Cyanocobalamin; Lidocaine Hydrochloride; Pyridoxine Hydrochloride; Thiamine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Calcium Pantothenate; Calcium Phosphate Dibasic; Colecalciferol; Copper Sulfate; Cyanocobalamin; Dl-Alpha Tocopheryl Acetate; Ferrous Fumarate; Magnesium Oxide; Manganese Sulfate; Nicotinamide; Po	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Herbal Nos; Levoglutamide; Lysine; Magnesium; Manganese; Retinol; Riboflavin; Selenium; Tocopherol; Zinc	0		1	(0.1)	1	(0.0)
Cyanocobalamin; Folic Acid; Thiamine Mononitrate; Thioctic Acid	1	(0.1)	0		1	(0.0)
Eucalyptus Globulus Oil; Pyridoxine Hydrochloride; Vitamin B1 Nos	1	(0.1)	0		1	(0.0)
Enzyme Preparations, A09aa	6	(0.3)	6	(0.3)	12	(0.3)
Pancreatin	5	(0.3)	3	(0.2)	8	(0.2)
Cellulase; Enzymes Nos; Pancreatic Digestive Enzyme Ta; Proctase; Sanactase	1	(0.1)	1	(0.1)	2	(0.1)
Pancreatin; Pepsin	0		1	(0.1)	1	(0.0)
Pancrelipase	0		1	(0.1)	1	(0.0)
Other General Anesthetics, N01ax	3	(0.2)	9	(0.5)	12	(0.3)
Propofol	3	(0.2)	8	(0.4)	11	(0.3)
Ketamine	0		1	(0.1)	1	(0.0)
Salicylic Acid And Derivatives, N02ba	6	(0.3)	6	(0.3)	12	(0.3)
Salicylamide	0		4	(0.2)	4	(0.1)
Acetylsalicylic Acid; Hydrotalcite	1	(0.1)	1	(0.1)	2	(0.1)
Acetylsalicylic Acid; Ascorbic Acid	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Ascorbic Acid; Caffeine	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Ascorbic Acid; Chlorphenamine Maleate; Moroxydine Hydrochloride; Phenylephrine Hydrochloride	1	(0.1)	0		1	(0.0)
Acetylsalicylic Acid; Chlorphenamine Maleate; Phenylephrine Bitartrate	0		1	(0.1)	1	(0.0)
Calcium Bromide; Cinchocaine Hydrochloride; Salicylate Sodium	1	(0.1)	0		1	(0.0)
Diflunisal	1	(0.1)	0		1	(0.0)
Bisphosphonates, M05ba	6	(0.3)	5	(0.3)	11	(0.3)
Alendronate Sodium	4	(0.2)	3	(0.2)	7	(0.2)
Bisphosphonates	1	(0.1)	0		1	(0.0)
Ibandronate Sodium	0		1	(0.1)	1	(0.0)
Risedronate Sodium	1	(0.1)	0		1	(0.0)
Zoledronic Acid	0		1	(0.1)	1	(0.0)
Folic Acid And Derivatives, B03bb	7	(0.4)	4	(0.2)	11	(0.3)
Folic Acid	6	(0.3)	3	(0.2)	9	(0.2)
Ascorbic Acid; Folic Acid; Mecobalamin; Nicotinamide	1	(0.1)	0		1	(0.0)
Doxylamine Succinate; Folic Acid; Pyridoxine Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Synthetic Anticholinergics, Esters With Tertiary Amino Group, A03aa	4	(0.2)	7	(0.4)	11	(0.3)
Dicycloverine	0		3	(0.2)	3	(0.1)
Mebeverine	2	(0.1)	1	(0.1)	3	(0.1)
Mebeverine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Alpha-D-Galactosidase; Simeticone; Trimebutine Maleate	0		1	(0.1)	1	(0.0)
Dicycloverine Hydrochloride	1	(0.1)	0		1	(0.0)
Trimebutine Maleate	0		1	(0.1)	1	(0.0)
Antiinflammatory Agents, Non-Steroids, S01bc	4	(0.2)	6	(0.3)	10	(0.3)
Nepafenac	4	(0.2)	6	(0.3)	10	(0.3)
Antineovascularisation Agents, S01la	6	(0.3)	4	(0.2)	10	(0.3)
Bevacizumab	3	(0.2)	4	(0.2)	7	(0.2)
Aflibercept	3	(0.2)	0		3	(0.1)
Beta Blocking Agents, Non-Selective, C07aa	2	(0.1)	8	(0.4)	10	(0.3)
Timolol Maleate	0		3	(0.2)	3	(0.1)
Propranolol Hydrochloride	0		2	(0.1)	2	(0.1)
Sotalol Hydrochloride	0		2	(0.1)	2	(0.1)
Timolol	1	(0.1)	1	(0.1)	2	(0.1)
Nadolol	1	(0.1)	0		1	(0.0)
Propranolol	0		1	(0.1)	1	(0.0)
Bioflavonoids, C05ca	4	(0.2)	6	(0.3)	10	(0.3)
Diosmin	3	(0.2)	4	(0.2)	7	(0.2)
Arnica Montana; Coumarin; Diosmin; Escin; Sitosterol	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Hesperidin Methyl Chalcone; Ruscus Aculeatus	0		1	(0.1)	1	(0.0)
Diosmin; Hesperidin	0		1	(0.1)	1	(0.0)
Indometacin; Troxerutin	0		1	(0.1)	1	(0.0)
Imidazole And Triazole Derivatives, D01ac	6	(0.3)	4	(0.2)	10	(0.3)
Efinaconazole	2	(0.1)	1	(0.1)	3	(0.1)
Luliconazole	2	(0.1)	0		2	(0.1)
Beclometasone Dipropionate; Clotrimazole	0		1	(0.1)	1	(0.0)
Clotrimazole; Hydrocortisone	0		1	(0.1)	1	(0.0)
Econazole Nitrate; Triamcinolone Acetonide	0		1	(0.1)	1	(0.0)
Hydrocortisone; Miconazole Nitrate	1	(0.1)	0		1	(0.0)
Lanoconazole	1	(0.1)	0		1	(0.0)
Papaverine And Derivatives, A03ad	6	(0.3)	4	(0.2)	10	(0.3)
Drotaverine Hydrochloride	3	(0.2)	4	(0.2)	7	(0.2)
Drotaverine	3	(0.2)	0		3	(0.1)
Purine Derivatives, C04ad	6	(0.3)	4	(0.2)	10	(0.3)
Pentoxifylline	6	(0.3)	4	(0.2)	10	(0.3)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12, A11db	4	(0.2)	6	(0.3)	10	(0.3)
Cyanocobalamin; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	2	(0.1)	1	(0.1)	3	(0.1)
Benfotiamine; Cyanocobalamin; Pyridoxine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Benfotiamine; Pyridoxine Hydrochloride	0		2	(0.1)	2	(0.1)
Pyridoxine Hydrochloride; Thiamine Mononitrate; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Pyridoxine Hydrochloride; Vitamin B1 Nos; Vitamin B12 Nos	1	(0.1)	0		1	(0.0)
Vitamin B1 In Combination With Vitamin B6 And/Or Vitamin B12	0		1	(0.1)	1	(0.0)
Combinations Of Various Lipid Modifying Agents, C10ba	3	(0.2)	6	(0.3)	9	(0.2)
Ezetimibe; Rosuvastatin Calcium	2	(0.1)	5	(0.3)	7	(0.2)
Atorvastatin Calcium; Ezetimibe	0		1	(0.1)	1	(0.0)
Fenofibrate; Rosuvastatin	1	(0.1)	0		1	(0.0)
Melatonin Receptor Agonists, N05ch	2	(0.1)	7	(0.4)	9	(0.2)
Melatonin	1	(0.1)	7	(0.4)	8	(0.2)
Ramelteon	1	(0.1)	0		1	(0.0)
Other Sclerosing Agents, C05bx	6	(0.3)	3	(0.2)	9	(0.2)
Calcium Dobesilate	6	(0.3)	3	(0.2)	9	(0.2)
Pertussis Vaccines, J07aj	5	(0.3)	4	(0.2)	9	(0.2)
Diphtheria Vaccine Toxoid; Pertussis Vaccine Acellular; Tetanus Vaccine Toxoid	4	(0.2)	2	(0.1)	6	(0.2)
Diphtheria Vaccine Toxoid; Pertussis Vaccine; Tetanus Vaccine Toxoid	0		2	(0.1)	2	(0.1)
Diphtheria Vaccine Toxoid; Pertussis Vaccine Acellular 3-Component; Tetanus Vaccine Toxoid	1	(0.1)	0		1	(0.0)
Tadalafil, G04be08	5	(0.3)	4	(0.2)	9	(0.2)
Tadalafil	5	(0.3)	4	(0.2)	9	(0.2)
Vitamin B-Complex, Plain, A11ea	3	(0.2)	6	(0.3)	9	(0.2)
Vitamin B Complex	3	(0.2)	5	(0.3)	8	(0.2)
Calcium Pantothenate; Cyanocobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Mononitrate	0		1	(0.1)	1	(0.0)
Adrenergics In Combinations With Anticholinergics Incl. Triple Combinations With Corticosteroids, R03al	4	(0.2)	4	(0.2)	8	(0.2)
Fenoterol Hydrobromide; Ipratropium Bromide	1	(0.1)	2	(0.1)	3	(0.1)
Beclometasone Dipropionate; Formoterol Fumarate; Glycopyrronium Bromide	0		1	(0.1)	1	(0.0)
Budesonide; Formoterol Fumarate; Glycopyrronium Bromide	1	(0.1)	0		1	(0.0)
Budesonide; Formoterol; Glycopyrronium	0		1	(0.1)	1	(0.0)
Fluticasone Furoate; Umeclidinium Bromide; Vilanterol Trifenatate	1	(0.1)	0		1	(0.0)
Glycopyrronium Bromide; Indacaterol Maleate	1	(0.1)	0		1	(0.0)
Ipratropium Bromide; Levosalbutamol Sulfate	0		1	(0.1)	1	(0.0)
Umeclidinium Bromide; Vilanterol Trifenatate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Anticholinergics, R03bb	6	(0.3)	2	(0.1)	8	(0.2)
Ipratropium	2	(0.1)	0		2	(0.1)
Ipratropium Bromide	2	(0.1)	0		2	(0.1)
Umeclidinium Bromide	1	(0.1)	1	(0.1)	2	(0.1)
Tiotropium	1	(0.1)	0		1	(0.0)
Umeclidinium	0		1	(0.1)	1	(0.0)
Antiinflammatory Preparations, Non-Steroids For Topical Use, M02aa	6	(0.3)	2	(0.1)	8	(0.2)
Felbinac	4	(0.2)	0		4	(0.1)
Diclofenac Diethylamine; Linum Usitatissimum Seed Oil; Menthol; Methyl Salicylate	1	(0.1)	1	(0.1)	2	(0.1)
Esflurbiprofen; Mentha Spp. Oil	1	(0.1)	0		1	(0.0)
Indometacin; Levomenthol; Tocopheryl Acetate	0		1	(0.1)	1	(0.0)
Corticosteroids, Potent (Group Iii), D07ac	6	(0.3)	2	(0.1)	8	(0.2)
Diflucortolone Valerate	2	(0.1)	1	(0.1)	3	(0.1)
Methylprednisolone Aceponate	2	(0.1)	1	(0.1)	3	(0.1)
Desoximetasone	2	(0.1)	0		2	(0.1)
Diflorasone Diacetate	1	(0.1)	0		1	(0.0)
Epinephrine, C01ca24	2	(0.1)	6	(0.3)	8	(0.2)
Epinephrine	2	(0.1)	5	(0.3)	7	(0.2)
Epinephrine Hydrochloride	0		1	(0.1)	1	(0.0)
Preparations With No Effect On Uric Acid Metabolism, M04ac	5	(0.3)	3	(0.2)	8	(0.2)
Colchicine	5	(0.3)	3	(0.2)	8	(0.2)
Prostaglandin Analogues, S01ee	4	(0.2)	4	(0.2)	8	(0.2)
Latanoprost	3	(0.2)	2	(0.1)	5	(0.1)
Bimatoprost	0		2	(0.1)	2	(0.1)
Tafluprost	1	(0.1)	0		1	(0.0)
Testosterone-5-Alpha Reductase Inhibitors, G04cb	5	(0.3)	3	(0.2)	8	(0.2)
Finasteride	4	(0.2)	2	(0.1)	6	(0.2)
Dutasteride	2	(0.1)	1	(0.1)	3	(0.1)
Trimethoprim And Derivatives, J01ea	4	(0.2)	4	(0.2)	8	(0.2)
Trimethoprim	4	(0.2)	4	(0.2)	8	(0.2)
Angiotensin Ii Receptor Blockers (Arbs) And Diuretics, C09da	2	(0.1)	5	(0.3)	7	(0.2)
Hydrochlorothiazide; Irbesartan	0		2	(0.1)	2	(0.1)
Hydrochlorothiazide; Losartan Potassium	0		2	(0.1)	2	(0.1)
Hydrochlorothiazide; Valsartan	1	(0.1)	1	(0.1)	2	(0.1)
Candesartan; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Carbonic Anhydrase Inhibitors, S01ec	1	(0.1)	6	(0.3)	7	(0.2)
Dorzolamide	1	(0.1)	2	(0.1)	3	(0.1)
Brimonidine Tartrate; Brinzolamide	0		2	(0.1)	2	(0.1)
Dorzolamide Hydrochloride	0		2	(0.1)	2	(0.1)
Brinzolamide	0		1	(0.1)	1	(0.0)
Digitalis Glycosides, C01aa	4	(0.2)	3	(0.2)	7	(0.2)
Digoxin	4	(0.2)	3	(0.2)	7	(0.2)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord), A02b	5	(0.3)	2	(0.1)	7	(0.2)
Teprenone	3	(0.2)	2	(0.1)	5	(0.1)
Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (Gord)	2	(0.1)	0		2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Drugs For Treatment Of Hyperkalemia And Hyperphosphatemia, V03ae	3	(0.2)	4	(0.2)	7	(0.2)
Calcium Polystyrene Sulfonate	2	(0.1)	3	(0.2)	5	(0.1)
Sevelamer	0		1	(0.1)	1	(0.0)
Sodium Zirconium Cyclosilicate	1	(0.1)	0		1	(0.0)
Drugs Used In Nicotine Dependence, N07ba	4	(0.2)	3	(0.2)	7	(0.2)
Nicotine	3	(0.2)	1	(0.1)	4	(0.1)
Nicotine Polacrilex	1	(0.1)	0		1	(0.0)
Varenicline	0		1	(0.1)	1	(0.0)
Varenicline Tartrate	0		1	(0.1)	1	(0.0)
Fenamates, M01ag	3	(0.2)	4	(0.2)	7	(0.2)
Mefenamic Acid	3	(0.2)	4	(0.2)	7	(0.2)
Neuraminidase Inhibitors, J05ah	5	(0.3)	2	(0.1)	7	(0.2)
Oseltamivir Phosphate	3	(0.2)	1	(0.1)	4	(0.1)
Oseltamivir	2	(0.1)	1	(0.1)	3	(0.1)
Other Vasodilators Used In Cardiac Diseases, C01dx	4	(0.2)	3	(0.2)	7	(0.2)
Sacubitril	3	(0.2)	2	(0.1)	5	(0.1)
Ligustrazine	0		1	(0.1)	1	(0.0)
Nicorandil	1	(0.1)	0		1	(0.0)
Synthetic Anticholinergics, Quaternary Ammonium Compounds, A03ab	4	(0.2)	3	(0.2)	7	(0.2)
Otilonium Bromide	2	(0.1)	1	(0.1)	3	(0.1)
Pipoxolan Hydrochloride	1	(0.1)	2	(0.1)	3	(0.1)
Timepidium Bromide	1	(0.1)	0		1	(0.0)
Tetanus Vaccines, J07am	5	(0.3)	2	(0.1)	7	(0.2)
Tetanus Vaccine	3	(0.2)	0		3	(0.1)
Tetanus Vaccine Toxoid	2	(0.1)	1	(0.1)	3	(0.1)
Diphtheria Vaccine Toxoid; Tetanus Vaccine Toxoid	0		1	(0.1)	1	(0.0)
3-Oxoandrosten (4) Derivatives, G03ba	3	(0.2)	3	(0.2)	6	(0.2)
Testosterone	3	(0.2)	1	(0.1)	4	(0.1)
Testosterone Enanthate	0		1	(0.1)	1	(0.0)
Testosterone Undecylenate	0		1	(0.1)	1	(0.0)
Ace Inhibitors And Calcium Channel Blockers, C09bb	1	(0.1)	5	(0.3)	6	(0.2)
Amlodipine Besilate; Perindopril Erbumine	0		2	(0.1)	2	(0.1)
Amlodipine Besilate; Ramipril	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Benazepril Hydrochloride	0		1	(0.1)	1	(0.0)
Amlodipine; Benazepril	0		1	(0.1)	1	(0.0)
Angiotensin Ii Receptor Blockers (Arbs) And Calcium Channel Blockers, C09db	3	(0.2)	3	(0.2)	6	(0.2)
Amlodipine Besilate; Telmisartan	0		2	(0.1)	2	(0.1)
Amlodipine Besilate; Azilsartan	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Irbesartan	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Valsartan	1	(0.1)	0		1	(0.0)
Amlodipine; Valsartan	0		1	(0.1)	1	(0.0)
Beta-Lactamase Sensitive Penicillins, J01ce	3	(0.2)	3	(0.2)	6	(0.2)
Phenoxymethylpenicillin	2	(0.1)	2	(0.1)	4	(0.1)
Phenoxymethylpenicillin Potassium	1	(0.1)	1	(0.1)	2	(0.1)
Bile Acids And Derivatives, A05aa	4	(0.2)	2	(0.1)	6	(0.2)
Ursodeoxycholic Acid	4	(0.2)	2	(0.1)	6	(0.2)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Calcium, Combinations With Vitamin D And/Or Other Drugs, A12ax	5	(0.3)	1	(0.1)	6	(0.2)
Calcium Carbonate; Colecalciferol	3	(0.2)	1	(0.1)	4	(0.1)
Calcium Carbonate; Colecalciferol; Menaquinone	1	(0.1)	0		1	(0.0)
Calcium Phosphate; Calcium Sodium Lactate; Ergocalciferol	1	(0.1)	0		1	(0.0)
Corticosteroids For Systemic Use, Combinations, H02bx	3	(0.2)	3	(0.2)	6	(0.2)
Betamethasone; Dexchlorpheniramine Maleate	2	(0.1)	2	(0.1)	4	(0.1)
Betamethasone Acetate; Sodium Phosphate Dibasic	1	(0.1)	0		1	(0.0)
Betamethasone; Chlorphenamine Maleate	0		1	(0.1)	1	(0.0)
Diazepines, Oxazepines, Thiazepines And Oxepines, N05ah	3	(0.2)	3	(0.2)	6	(0.2)
Quetiapine Fumarate	3	(0.2)	2	(0.1)	5	(0.1)
Olanzapine	0		1	(0.1)	1	(0.0)
Direct Thrombin Inhibitors, B01ae	3	(0.2)	3	(0.2)	6	(0.2)
Dabigatran Etexilate Mesilate	2	(0.1)	1	(0.1)	3	(0.1)
Dabigatran Etexilate	0		2	(0.1)	2	(0.1)
Dabigatran	1	(0.1)	0		1	(0.0)
Iron In Other Combinations, B03ae	5	(0.3)	1	(0.1)	6	(0.2)
Ascorbic Acid; Cyanocobalamin; Docusate Sodium; Ferrous Fumarate; Folic Acid; Tocopheryl Acid Succinate	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Cyanocobalamin; Folic Acid; Iron	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Ferrous Sulfate; Folic Acid; Protease Nos	1	(0.1)	0		1	(0.0)
Biotin; Calcium Pantothenate; Folic Acid; Iron Pentacarbonyl; Mecobalamin; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Vitamin B1 Nos	0		1	(0.1)	1	(0.0)
Cyanocobalamin; Ferrous Fumarate; Folic Acid	1	(0.1)	0		1	(0.0)
Other Antidiarrheals, A07xa	3	(0.2)	3	(0.2)	6	(0.2)
Albumin Tannate	1	(0.1)	2	(0.1)	3	(0.1)
Chloroform And Morphine Tincture; Kaolin; Pectin; Potassium Chloride; Sodium Chloride; Sodium Lactate	1	(0.1)	0		1	(0.0)
Citrus Aurantium Peel; Creosote; Glycyrrhiza Spp. Root; Phellodendron Spp. Bark; Uncaria Gambir Leaf With Twig	1	(0.1)	0		1	(0.0)
Racecadotril	0		1	(0.1)	1	(0.0)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids, M01ax	3	(0.2)	3	(0.2)	6	(0.2)
Clonixin Lysinate	2	(0.1)	0		2	(0.1)
Angelica Gigas Root; Aronia Melanocarpa Fruit; Ascorbic Acid; Bromelains; Camellia Sinensis Leaf; Chondroitin Sulfate; Curcuma Longa Root; Glucosamine Hydrochloride; Harpagophytum Procumbens Root; Manganese; Me	0		1	(0.1)	1	(0.0)
Diacerein	0		1	(0.1)	1	(0.0)
Glucosamine Sulfate; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antiinflammatory And Antirheumatic Agents, Non-Steroids	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Capillary Stabilizing Agents, C05cx	2	(0.1)	4	(0.2)	6	(0.2)
Hesperidin	2	(0.1)	1	(0.1)	3	(0.1)
Escin	0		1	(0.1)	1	(0.0)
Escin Sodium	0		1	(0.1)	1	(0.0)
Hesperidin Methyl Chalcone	0		1	(0.1)	1	(0.0)
Other Cold Preparations, R05x	2	(0.1)	4	(0.2)	6	(0.2)
Ascorbic Acid; Gentiana Lutea Root; Primula Spp. Flower; Rumex Acetosa; Sambucus Nigra Flower; Verbena Officinalis Herb	1	(0.1)	3	(0.2)	4	(0.1)
Camphor; Eucalyptus Globulus Oil; Juniperus Virginiana Wood Oil; Menthol; Myristica Fragrans Oil; Pinus Nigra Oil; Thymol	0		1	(0.1)	1	(0.0)
Honey; Plantago Lanceolata Fluid Extract; Thymus Serpyllum Fluid Extract; Thymus Vulgaris Fluid Extract	1	(0.1)	0		1	(0.0)
Other Intestinal Antiinfectives, A07ax	1	(0.1)	5	(0.3)	6	(0.2)
Nifuroxazide	1	(0.1)	4	(0.2)	5	(0.1)
Berberine Hydrochloride; Geranium Thunbergii Herb	0		1	(0.1)	1	(0.0)
Oxazol, Thiazine, And Triazine Derivatives, M03bb	4	(0.2)	2	(0.1)	6	(0.2)
Chlorzoxazone	3	(0.2)	1	(0.1)	4	(0.1)
Chlorzoxazone; Ibuprofen; Paracetamol	0		1	(0.1)	1	(0.0)
Metaxalone	1	(0.1)	0		1	(0.0)
Preparations With Salicylic Acid Derivatives, M02ac	2	(0.1)	4	(0.2)	6	(0.2)
Diethylamine Salicylate	1	(0.1)	2	(0.1)	3	(0.1)
Camphor; Capsicum Spp. Extract; Methyl Salicylate	1	(0.1)	0		1	(0.0)
Camphor; Enoxolone; Eucalyptus Globulus Oil; Glycol Salicylate; Menthol; Methyl Salicylate	0		1	(0.1)	1	(0.0)
Trolamine Salicylate	0		1	(0.1)	1	(0.0)
Progestogens, G03ac	4	(0.2)	2	(0.1)	6	(0.2)
Desogestrel	1	(0.1)	0		1	(0.0)
Drospirenone	1	(0.1)	0		1	(0.0)
Ethinylestradiol; Ferrous Fumarate; Norethisterone Acetate	0		1	(0.1)	1	(0.0)
Ethinylestradiol; Levonorgestrel	1	(0.1)	0		1	(0.0)
Etonogestrel	0		1	(0.1)	1	(0.0)
Medroxyprogesterone	1	(0.1)	0		1	(0.0)
Norethisterone	1	(0.1)	0		1	(0.0)
Norethisterone Acetate	1	(0.1)	0		1	(0.0)
Pyrethrines, Incl. Synthetic Compounds, P03ac	2	(0.1)	4	(0.2)	6	(0.2)
Permethrin	2	(0.1)	4	(0.2)	6	(0.2)
Viral Vaccines, J07b	1	(0.1)	5	(0.3)	6	(0.2)
Viral Vaccines	1	(0.1)	5	(0.3)	6	(0.2)
Alpha- And Beta-Adrenoreceptor Agonists, R03ca	0		5	(0.3)	5	(0.1)
Methylephedrine Hydrochloride-Dl	0		5	(0.3)	5	(0.1)
Angiotensin Ii Receptor Blockers (Arbs), Other Combinations, C09dx	3	(0.2)	2	(0.1)	5	(0.1)
Sacubitril; Valsartan	3	(0.2)	2	(0.1)	5	(0.1)
Antiinfectives For Treatment Of Acne, D10af	2	(0.1)	3	(0.2)	5	(0.1)
Nadifloxacin	1	(0.1)	3	(0.2)	4	(0.1)
Benzoyl Peroxide; Clindamycin Phosphate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Combinations And Complexes Of Aluminium, Calcium And Magnesium Compounds, A02ad	2	(0.1)	3	(0.2)	5	(0.1)
Aluminium Hydroxide Gel; Magnesium Hydroxide	0		1	(0.1)	1	(0.0)
Aluminium Hydroxide; Magnesium Hydroxide	0		1	(0.1)	1	(0.0)
Aluminium Magnesium Silicate	0		1	(0.1)	1	(0.0)
Calcium Carbonate; Calcium Phosphate; Kaolin; Magnesium Carbonate; Magnesium Hydroxide; Magnesium Oxide	1	(0.1)	0		1	(0.0)
Hydrotalcite	1	(0.1)	0		1	(0.0)
Enzymes, C04af	1	(0.1)	4	(0.2)	5	(0.1)
Kallidinogenase	1	(0.1)	4	(0.2)	5	(0.1)
Fourth-Generation Cephalosporins, J01de	4	(0.2)	1	(0.1)	5	(0.1)
Cefepime	2	(0.1)	1	(0.1)	3	(0.1)
Cefepime Hydrochloride	2	(0.1)	0		2	(0.1)
Cefepime Hydrochloride; Sulbactam Sodium	0		1	(0.1)	1	(0.0)
Interleukin Inhibitors, L04ac	3	(0.2)	2	(0.1)	5	(0.1)
Olokizumab	3	(0.2)	0		3	(0.1)
Netakimab	0		1	(0.1)	1	(0.0)
Tocilizumab	0		1	(0.1)	1	(0.0)
Local Anesthetics, S01ha	1	(0.1)	4	(0.2)	5	(0.1)
Proxymetacaine Hydrochloride	1	(0.1)	3	(0.2)	4	(0.1)
Benzalkonium Chloride; Lidocaine Hydrochloride; Methylcellulose	0		1	(0.1)	1	(0.0)
Macrolides, J01fa	2	(0.1)	3	(0.2)	5	(0.1)
Roxithromycin	2	(0.1)	2	(0.1)	4	(0.1)
Spiramycin	0		1	(0.1)	1	(0.0)
Other Alimentary Tract And Metabolism Products, A16a	3	(0.2)	2	(0.1)	5	(0.1)
Clostridium Butyricum	3	(0.2)	2	(0.1)	5	(0.1)
Other Antibiotics For Topical Use, D06ax	1	(0.1)	4	(0.2)	5	(0.1)
Bacitracin Zinc; Lidocaine; Neomycin Sulfate; Polymyxin B Sulfate	0		1	(0.1)	1	(0.0)
Bacitracin; Colistin Sulfate	0		1	(0.1)	1	(0.0)
Chloramphenicol; Methyluracil	0		1	(0.1)	1	(0.0)
Hinokitiol	0		1	(0.1)	1	(0.0)
Lidocaine Hydrochloride; Primycin Sulfate	1	(0.1)	0		1	(0.0)
Other Antiepileptics, N03ax	4	(0.2)	1	(0.1)	5	(0.1)
Topiramate	3	(0.2)	1	(0.1)	4	(0.1)
Levetiracetam	1	(0.1)	0		1	(0.0)
Other Antipsychotics, N05ax	3	(0.2)	2	(0.1)	5	(0.1)
Aripiprazole	2	(0.1)	1	(0.1)	3	(0.1)
Cariprazine	0		1	(0.1)	1	(0.0)
Prothipendyl	1	(0.1)	0		1	(0.0)
Other Drugs For Constipation, A06ax	2	(0.1)	3	(0.2)	5	(0.1)
Elobixibat	1	(0.1)	1	(0.1)	2	(0.1)
Linaclotide	1	(0.1)	1	(0.1)	2	(0.1)
Lubiprostone	0		1	(0.1)	1	(0.0)
Other Hypnotics And Sedatives, N05cm	2	(0.1)	3	(0.2)	5	(0.1)
Suvorexant	1	(0.1)	1	(0.1)	2	(0.1)
Bromisoval	0		1	(0.1)	1	(0.0)
Dexmedetomidine Hydrochloride	0		1	(0.1)	1	(0.0)
Lemborexant	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Immunostimulants, L03ax	1	(0.1)	4	(0.2)	5	(0.1)
Arabinogalactan; Ascorbic Acid; Beta Glucan; Calcium Carbonate; Calcium Pantothenate; Calcium Phosphate; Calcium Phosphate Monobasic; Chromium Picolinate; Colecalciferol; Cyanocobalamin; Folic Acid; Magnesium Ca	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Colecalciferol; Selenium; Zinc	1	(0.1)	0		1	(0.0)
Luminol Sodium	0		1	(0.1)	1	(0.0)
Meglumine Acridonacetate	0		1	(0.1)	1	(0.0)
Transfer Factor	0		1	(0.1)	1	(0.0)
Other Immunosuppressants, L04ax	3	(0.2)	2	(0.1)	5	(0.1)
Methotrexate	3	(0.2)	2	(0.1)	5	(0.1)
Other Intestinal Adsorbents, A07bc	2	(0.1)	3	(0.2)	5	(0.1)
Diosmectite	1	(0.1)	1	(0.1)	2	(0.1)
Gelatin Tannate	0		1	(0.1)	1	(0.0)
Kaolin	1	(0.1)	0		1	(0.0)
Polymethylsiloxane Polyhydrate	0		1	(0.1)	1	(0.0)
Other Systemic Hemostatics, B02bx	4	(0.2)	1	(0.1)	5	(0.1)
Carbazochrome Sodium Sulfonate	3	(0.2)	1	(0.1)	4	(0.1)
Carbazochrome	1	(0.1)	0		1	(0.0)
Etamsilate	1	(0.1)	0		1	(0.0)
Phenothiazine Derivatives, R06ad	0		5	(0.3)	5	(0.1)
Promethazine Methylene Disalicylate	0		4	(0.2)	4	(0.1)
Thiethylperazine Maleate	0		1	(0.1)	1	(0.0)
Phenylalkylamine Derivatives, C08da	3	(0.2)	2	(0.1)	5	(0.1)
Verapamil Hydrochloride	3	(0.2)	1	(0.1)	4	(0.1)
Verapamil	0		1	(0.1)	1	(0.0)
Pyrimidine Analogues, L01bc	3	(0.2)	2	(0.1)	5	(0.1)
Capecitabine	1	(0.1)	1	(0.1)	2	(0.1)
Fluorouracil	2	(0.1)	0		2	(0.1)
Gemcitabine	0		1	(0.1)	1	(0.0)
Tonics, A13a	2	(0.1)	3	(0.2)	5	(0.1)
Dietary Supplement	2	(0.1)	1	(0.1)	3	(0.1)
Oxyethylammonium Methylphenoxyacetate	0		2	(0.1)	2	(0.1)
Vitamin K Antagonists, B01aa	2	(0.1)	3	(0.2)	5	(0.1)
Warfarin	2	(0.1)	2	(0.1)	4	(0.1)
Warfarin Sodium	0		1	(0.1)	1	(0.0)
Vitamins With Minerals, A11jb	4	(0.2)	1	(0.1)	5	(0.1)
Vitamins With Minerals	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Biotin; Copper; Retinol; Zinc	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium Carbonate; Calcium Pantothenate; Calcium Phosphate; Chromium; Cyanocobalamin; Folic Acid; Magnesium Carbonate; Magnesium Hydroxide; Manganese Gluconate; Nicotinic Acid; Potassium Bicarbona	1	(0.1)	0		1	(0.0)
Vitamins Nos; Zinc Sulfate	1	(0.1)	0		1	(0.0)
Xanthines, R03da	1	(0.1)	4	(0.2)	5	(0.1)
Diprophylline	1	(0.1)	1	(0.1)	2	(0.1)
Ambroxol Acefyllinate	0		1	(0.1)	1	(0.0)
Aminophylline	0		1	(0.1)	1	(0.0)
Doxofylline	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ace Inhibitors And Diuretics, C09ba	3	(0.2)	1	(0.1)	4	(0.1)
Captopril; Hydrochlorothiazide	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Lisinopril	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Ramipril	0		1	(0.1)	1	(0.0)
Indapamide; Perindopril Erbumine	1	(0.1)	0		1	(0.0)
Antiarrhythmics, Class Ic, C01bc	4	(0.2)	0		4	(0.1)
Propafenone Hydrochloride	3	(0.2)	0		3	(0.1)
Flecainide Acetate	1	(0.1)	0		1	(0.0)
Antidiarrheal Microorganisms, A07f	4	(0.2)	0		4	(0.1)
Antidiarrheal Microorganisms	4	(0.2)	0		4	(0.1)
Aromatase Inhibitors, L02bg	1	(0.1)	3	(0.2)	4	(0.1)
Anastrozole	1	(0.1)	1	(0.1)	2	(0.1)
Letrozole	0		2	(0.1)	2	(0.1)
Azaspirodecanedione Derivatives, N05be	3	(0.2)	1	(0.1)	4	(0.1)
Buspirone	3	(0.2)	0		3	(0.1)
Buspirone Hydrochloride	0		1	(0.1)	1	(0.0)
Benzodiazepine Derivatives, N03ae	1	(0.1)	3	(0.2)	4	(0.1)
Clonazepam	1	(0.1)	3	(0.2)	4	(0.1)
Beta Blocking Agents, S01ed	1	(0.1)	3	(0.2)	4	(0.1)
Dorzolamide Hydrochloride; Timolol Maleate	1	(0.1)	2	(0.1)	3	(0.1)
Carteolol Hydrochloride; Latanoprost	0		2	(0.1)	2	(0.1)
Corticosteroids, Moderately Potent (Group Ii), D07ab	1	(0.1)	3	(0.2)	4	(0.1)
Dexamethasone Propionate	1	(0.1)	3	(0.2)	4	(0.1)
Corticosteroids, Potent, Combinations With Antibiotics, D07cc	2	(0.1)	2	(0.1)	4	(0.1)
Betamethasone Valerate; Fusidic Acid	1	(0.1)	1	(0.1)	2	(0.1)
Betamethasone Valerate; Clioquinol; Gentamicin Sulfate; Tolnaftate	1	(0.1)	0		1	(0.0)
Clotrimazole; Fusidic Acid; Mometasone	0		1	(0.1)	1	(0.0)
Dopamine Agonists, N04bc	2	(0.1)	2	(0.1)	4	(0.1)
Pramipexole Dihydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Pramipexole	1	(0.1)	0		1	(0.0)
Ropinirole Hydrochloride	0		1	(0.1)	1	(0.0)
Electrolyte Solutions, B05xa	1	(0.1)	3	(0.2)	4	(0.1)
Electrolyte Solutions [Umbrella Term]	1	(0.1)	3	(0.2)	4	(0.1)
Hydrazinophthalazine Derivatives, C02db	2	(0.1)	2	(0.1)	4	(0.1)
Hydralazine	2	(0.1)	2	(0.1)	4	(0.1)
Insulins And Analogues For Injection, Intermediate- Or Long-Acting Combined With Fast-Acting, A10ad	0		4	(0.2)	4	(0.1)
Insulin	0		1	(0.1)	1	(0.0)
Insulin Aspart; Insulin Degludec	0		1	(0.1)	1	(0.0)
Insulin Human; Insulin Human Injection, Isophane	0		1	(0.1)	1	(0.0)
Insulin; Isophane Insulin	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Multivitamins With Minerals, A11aa	1	(0.1)	3	(0.2)	4	(0.1)
Ascorbic Acid; Biotin; Calcium Pantothenate; Calcium Phosphate Dibasic; Chromic Chloride; Colecalciferol; Cupric Oxide; Ferrous Sulfate; Folic Acid; Magnesium Oxide; Manganese Chloride; Mecobalamin; Nicotinamide;	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Calcium; Colecalciferol; Copper; Cyanocobalamin; Folic Acid; Iron; Nicotinamide; Pyridoxine Hydrochloride; Retinol; Riboflavin; Thiamine Hydrochloride; Tocopherol; Zinc	1	(0.1)	0		1	(0.0)
Ascorbic Acid; Chromium; Copper; Cyanocobalamin; Folic Acid; Iodine; Magnesium; Manganese; Molybdenum; Nicotinic Acid; Pantothenic Acid; Potassium; Pyridoxine Hydrochloride; Retinol; Riboflavin; Selenium; Thiamine; To	0		1	(0.1)	1	(0.0)
Multivitamins With Minerals [Umbrella Term]	0		1	(0.1)	1	(0.0)
Natural And Semisynthetic Estrogens, Plain, G03ca	2	(0.1)	2	(0.1)	4	(0.1)
Estradiol	1	(0.1)	0		1	(0.0)
Estradiol Hemihydrate; Norethisterone Acetate	0		1	(0.1)	1	(0.0)
Estradiol; Norethisterone Acetate	1	(0.1)	0		1	(0.0)
Estriol	0		1	(0.1)	1	(0.0)
Other Analgesics And Antipyretics, N02bg	2	(0.1)	2	(0.1)	4	(0.1)
Mirogabalin Besilate	1	(0.1)	2	(0.1)	3	(0.1)
Nefopam	1	(0.1)	0		1	(0.0)
Other Urologicals, G04bx	2	(0.1)	2	(0.1)	4	(0.1)
Phenazopyridine	1	(0.1)	2	(0.1)	3	(0.1)
Phenazopyridine Hydrochloride	1	(0.1)	0		1	(0.0)
Platinum Compounds, L01xa	3	(0.2)	1	(0.1)	4	(0.1)
Oxaliplatin	3	(0.2)	0		3	(0.1)
Carboplatin	0		1	(0.1)	1	(0.0)
Selective Immunosuppressants, L04aa	2	(0.1)	2	(0.1)	4	(0.1)
Baricitinib	1	(0.1)	1	(0.1)	2	(0.1)
Tofacitinib	0		1	(0.1)	1	(0.0)
Tofacitinib Citrate	1	(0.1)	0		1	(0.0)
Sulfur-Containing Imidazole Derivatives, H03bb	0		4	(0.2)	4	(0.1)
Thiamazole	0		4	(0.2)	4	(0.1)
Adrenergic And Dopaminergic Agents, C01ca	2	(0.1)	1	(0.1)	3	(0.1)
Norepinephrine	1	(0.1)	1	(0.1)	2	(0.1)
Dopamine	1	(0.1)	0		1	(0.0)
Anticholinesterases, N06da	0		3	(0.2)	3	(0.1)
Ipidacrine	0		2	(0.1)	2	(0.1)
Donepezil Hydrochloride	0		1	(0.1)	1	(0.0)
Rivastigmine	0		1	(0.1)	1	(0.0)
Antidotes, V03ab	1	(0.1)	2	(0.1)	3	(0.1)
Flumazenil	1	(0.1)	1	(0.1)	2	(0.1)
Sugammadex Sodium	0		1	(0.1)	1	(0.0)
Antiseptics, R02aa	2	(0.1)	1	(0.1)	3	(0.1)
Amylmetacresol; Dichlorobenzyl Alcohol	2	(0.1)	0		2	(0.1)
Benzoxonium Chloride; Lidocaine Hydrochloride	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Beta-Lactamase Resistant Penicillins, J01cf	2	(0.1)	1	(0.1)	3	(0.1)
Cloxacillin	0		1	(0.1)	1	(0.0)
Dicloxacillin	1	(0.1)	0		1	(0.0)
Dicloxacillin Sodium Monohydrate	1	(0.1)	0		1	(0.0)
Flucloxacillin	1	(0.1)	0		1	(0.0)
Carbapenems, J01dh	0		3	(0.2)	3	(0.1)
Meropenem	0		2	(0.1)	2	(0.1)
Ertapenem Sodium	0		1	(0.1)	1	(0.0)
Meropenem Trihydrate	0		1	(0.1)	1	(0.0)
Corticosteroids For Systemic Use, H02	2	(0.1)	1	(0.1)	3	(0.1)
Steroids	2	(0.1)	0		2	(0.1)
Corticosteroids	0		1	(0.1)	1	(0.0)
Corticosteroids, C05aa	1	(0.1)	2	(0.1)	3	(0.1)
Escherichia Coli; Hydrocortisone	1	(0.1)	1	(0.1)	2	(0.1)
Cinchocaine Hydrochloride; Menthol; Prednisolone; Ruscogenin; Zinc Oxide	0		1	(0.1)	1	(0.0)
Diflucortolone Valerate; Lidocaine	0		1	(0.1)	1	(0.0)
Corticosteroids, Weak, Combinations With Antibiotics, D07ca	1	(0.1)	2	(0.1)	3	(0.1)
Chloramphenicol; Neomycin Sulfate; Prednisolone	1	(0.1)	0		1	(0.0)
Diphenhydramine Hydrochloride; Hydrocortisone Acetate; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Hydrocortisone; Natamycin; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Enzymes, B01ad	1	(0.1)	2	(0.1)	3	(0.1)
Alteplase	0		2	(0.1)	2	(0.1)
Hydroxytyrosol; Nattokinase	1	(0.1)	0		1	(0.0)
Fatty Acid Derivatives, N03ag	0		3	(0.2)	3	(0.1)
Valproate Sodium	0		2	(0.1)	2	(0.1)
Gamma-Aminobutyric Acid; Nicotinic Acid	0		1	(0.1)	1	(0.0)
Halogenated Hydrocarbons, N01ab	1	(0.1)	2	(0.1)	3	(0.1)
Sevoflurane	0		2	(0.1)	2	(0.1)
Desflurane	1	(0.1)	0		1	(0.0)
Homeopathic Preparation, V91	1	(0.1)	2	(0.1)	3	(0.1)
Bradykinin Antibodies; Histamin Antibodies; Morphine Antibodies	1	(0.1)	2	(0.1)	3	(0.1)
Liver Therapy, A05ba	1	(0.1)	2	(0.1)	3	(0.1)
Phospholipids Soybean	1	(0.1)	1	(0.1)	2	(0.1)
Inosine; Meglumine; Methionine; Nicotinamide; Succinic Acid	0		1	(0.1)	1	(0.0)
Multivitamins, Other Combinations, A11ab	1	(0.1)	2	(0.1)	3	(0.1)
Ascorbic Acid; Betacarotene; Biotin; Calcium; Carbohydrates Nos; Chloride; Choline; Chromium; Copper; Cyanocobalamin; Fats Nos; Fibre, Dietary; Fluorine; Folic Acid; Iodine; Iron; Magnesium; Manganese; Molybdenum; Nicot	0		1	(0.1)	1	(0.0)
Ascorbic Acid; Ergocalciferol; Folic Acid; Nicotinamide; Panthenol; Retinol; Riboflavin; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Multivitamins, Other Combinations	1	(0.1)	0		1	(0.0)
Nasal Decongestants For Systemic Use, R01b	2	(0.1)	1	(0.1)	3	(0.1)
Nasal Decongestants For Systemic Use	2	(0.1)	1	(0.1)	3	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Opioid Anesthetics, N01ah	0		3	(0.2)	3	(0.1)
Alfentanil Hydrochloride	0		1	(0.1)	1	(0.0)
Remifentanil	0		1	(0.1)	1	(0.0)
Remifentanil Hydrochloride	0		1	(0.1)	1	(0.0)
Other Agents For Local Oral Treatment, A01ad	2	(0.1)	1	(0.1)	3	(0.1)
Butyl Aminobenzoate; Eugenol; Iodoform	0		1	(0.1)	1	(0.0)
Cetrimide; Lidocaine; Tannic Acid; Zinc Chloride	1	(0.1)	0		1	(0.0)
Rheum Spp.; Salicylic Acid	1	(0.1)	0		1	(0.0)
Other Drugs Affecting Bone Structure And Mineralization, M05bx	2	(0.1)	1	(0.1)	3	(0.1)
Denosumab	2	(0.1)	1	(0.1)	3	(0.1)
Other Parasympathomimetics, N07ax	2	(0.1)	1	(0.1)	3	(0.1)
Choline Alfoscerate	2	(0.1)	1	(0.1)	3	(0.1)
Other Quinolones, J01mb	2	(0.1)	1	(0.1)	3	(0.1)
Nalidixic Acid	2	(0.1)	1	(0.1)	3	(0.1)
Selective Serotonin (5ht1) Agonists, N02cc	0		3	(0.2)	3	(0.1)
Eletriptan Hydrobromide	0		1	(0.1)	1	(0.0)
Naratriptan	0		1	(0.1)	1	(0.0)
Sumatriptan Succinate	0		1	(0.1)	1	(0.0)
Solutions For Parenteral Nutrition, B05ba	1	(0.1)	2	(0.1)	3	(0.1)
Amino Acids Nos; Calcium Chloride; Electrolytes Nos; Glucose; Lipids Nos	0		1	(0.1)	1	(0.0)
Amino Acids Nos; Electrolytes Nos; Glucose; Thiamine Hydrochloride	1	(0.1)	0		1	(0.0)
Amino Acids Nos; Glucose; Lipids Nos	0		1	(0.1)	1	(0.0)
Substituted Alkylamines, R06ab	2	(0.1)	1	(0.1)	3	(0.1)
Dexchlorpheniramine	1	(0.1)	1	(0.1)	2	(0.1)
Dexchlorpheniramine Maleate	1	(0.1)	0		1	(0.0)
Vitamin B-Complex With Vitamin C, A11eb	2	(0.1)	1	(0.1)	3	(0.1)
Ascorbic Acid; Dexpanthenol; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	2	(0.1)	0		2	(0.1)
Ascorbic Acid; Biotin; Calcium Pantothenate; Folic Acid; Nicotinamide; Nicotinic Acid; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride; Vitamin B12 Nos	0		1	(0.1)	1	(0.0)
Vitamin D Tablet, A11cc04	0		3	(0.2)	3	(0.1)
Calcitriol	0		3	(0.2)	3	(0.1)
Ace Inhibitors, Other Combinations, C09bx	1	(0.1)	1	(0.1)	2	(0.1)
Amlodipine Besilate; Indapamide; Perindopril Arginine	1	(0.1)	1	(0.1)	2	(0.1)
Agents For Dermatitis, Excluding Corticosteroids, D11ah	1	(0.1)	1	(0.1)	2	(0.1)
Delgocitinib	0		1	(0.1)	1	(0.0)
Pimecrolimus	1	(0.1)	0		1	(0.0)
Aldose Reductase Inhibitors, A10xa	1	(0.1)	1	(0.1)	2	(0.1)
Epalrestat	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Antacids With Antiflatulents, A02af	2	(0.1)	0		2	(0.1)
Aluminium Hydroxide; Dicycloverine Hydrochloride; Magnesium Oxide; Simeticone	1	(0.1)	0		1	(0.0)
Aluminium Hydroxide; Magnesium Hydroxide; Simeticone	1	(0.1)	0		1	(0.0)
Antacids With Sodium Bicarbonate, A02ah	1	(0.1)	1	(0.1)	2	(0.1)
Acorus Calamus Var. Angustatus Rhizome; Bismuth Subnitrate; Citrus Aurantium Fruit Peel; Glycyrrhiza Spp. Root With Rhizome; Magnesium Carbonate; Magnesium Oxide; Rheum Spp. Root With Rhizome; Sodium Bicarbo	0		1	(0.1)	1	(0.0)
Acorus Calamus; Bismuth Subnitrate; Magnesium Carbonate; Rhamnus Frangula; Sodium Bicarbonate	1	(0.1)	0		1	(0.0)
Antacids, A02a	1	(0.1)	1	(0.1)	2	(0.1)
Antacids	1	(0.1)	1	(0.1)	2	(0.1)
Antibiotics, R02ab	2	(0.1)	0		2	(0.1)
Benzalkonium Chloride; Benzocaine; Tyrothricin	1	(0.1)	0		1	(0.0)
Cetylpyridinium Chloride; Gramicidin S Hydrochloride	1	(0.1)	0		1	(0.0)
Benzimidazole Derivatives, P02ca	1	(0.1)	1	(0.1)	2	(0.1)
Albendazole	1	(0.1)	1	(0.1)	2	(0.1)
Benzothiazepine Derivatives, C08db	1	(0.1)	1	(0.1)	2	(0.1)
Diltiazem Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Diltiazem	0		1	(0.1)	1	(0.0)
Bile Acid Sequestrants, C10ac	1	(0.1)	1	(0.1)	2	(0.1)
Colesevelam Hydrochloride	0		1	(0.1)	1	(0.0)
Colestipol Hydrochloride	1	(0.1)	0		1	(0.0)
Blood Substitutes And Perfusion Solutions, B05	2	(0.1)	0		2	(0.1)
Carbohydrates Nos; Potassium Chloride; Sodium Chloride; Sodium Lactate	2	(0.1)	0		2	(0.1)
Calcitonin Gene-Related Peptide (Cgrp) Antagonists, N02cd	1	(0.1)	1	(0.1)	2	(0.1)
Erenumab	0		1	(0.1)	1	(0.0)
Ubrogepant	1	(0.1)	0		1	(0.0)
Colony Stimulating Factors, L03aa	2	(0.1)	0		2	(0.1)
Filgrastim	1	(0.1)	0		1	(0.0)
Pegfilgrastim	1	(0.1)	0		1	(0.0)
Combinations For Eradication Of Helicobacter Pylori, A02bd	1	(0.1)	1	(0.1)	2	(0.1)
Amoxicillin Trihydrate; Clarithromycin; Vonoprazan Fumarate	1	(0.1)	1	(0.1)	2	(0.1)
Amoxicillin Trihydrate; Metronidazole; Vonoprazan Fumarate	0		1	(0.1)	1	(0.0)
Combinations Of Antibacterials, J01ra	2	(0.1)	0		2	(0.1)
Azithromycin; Bacillus Coagulans; Cefixime	1	(0.1)	0		1	(0.0)
Cefixime; Ofloxacin	1	(0.1)	0		1	(0.0)
Combinations Of Oral Blood Glucose Lowering Drugs, A10bd	1	(0.1)	1	(0.1)	2	(0.1)
Glibenclamide; Metformin Hydrochloride	1	(0.1)	0		1	(0.0)
Metformin; Teneligliptin	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Corticosteroids And Antiinfectives In Combination, S02ca	1	(0.1)	1	(0.1)	2	(0.1)
Acetic Acid; Dexamethasone; Neomycin Sulfate	0		1	(0.1)	1	(0.0)
Beclometasone Dipropionate; Chloramphenicol; Clotrimazole; Lidocaine Hydrochloride	1	(0.1)	0		1	(0.0)
Corticosteroids, Potent, Other Combinations, D07xc	0		2	(0.1)	2	(0.1)
Betamethasone Dipropionate; Salicylic Acid	0		1	(0.1)	1	(0.0)
Mometasone Furoate; Salicylic Acid	0		1	(0.1)	1	(0.0)
Cough And Cold Preparations, R05	1	(0.1)	1	(0.1)	2	(0.1)
Cough And Cold Preparations	0		1	(0.1)	1	(0.0)
Potassium Cresolsulfonate	1	(0.1)	0		1	(0.0)
Dermatologicals, D	1	(0.1)	1	(0.1)	2	(0.1)
Dermatologicals	1	(0.1)	1	(0.1)	2	(0.1)
Dopa And Dopa Derivatives, N04ba	1	(0.1)	1	(0.1)	2	(0.1)
Benserazide Hydrochloride	1	(0.1)	0		1	(0.0)
Benserazide Hydrochloride; Levodopa	0		1	(0.1)	1	(0.0)
Levodopa	1	(0.1)	0		1	(0.0)
Enzymes, B06aa	2	(0.1)	0		2	(0.1)
Bromelains; Papain; Rutoside	1	(0.1)	0		1	(0.0)
Vorhyaluronidase Alfa	1	(0.1)	0		1	(0.0)
Ethers, Chemically Close To Antihistamines, M03bc	1	(0.1)	1	(0.1)	2	(0.1)
Diclofenac Sodium; Orphenadrine Citrate	1	(0.1)	0		1	(0.0)
Orphenadrine Citrate	0		1	(0.1)	1	(0.0)
Fluoroquinolones, J01ma	2	(0.1)	0		2	(0.1)
Garenoxacin Mesilate	1	(0.1)	0		1	(0.0)
Pefloxacin	1	(0.1)	0		1	(0.0)
General Nutrients, V06	1	(0.1)	1	(0.1)	2	(0.1)
General Nutrients	1	(0.1)	1	(0.1)	2	(0.1)
Glycogenolytic Hormones, H04aa	0		2	(0.1)	2	(0.1)
Glucagon	0		2	(0.1)	2	(0.1)
Hepatitis Vaccines, J07bc	1	(0.1)	1	(0.1)	2	(0.1)
Hepatitis A Vaccine Inact; Hepatitis B Vaccine Rhbsag (Yeast)	1	(0.1)	0		1	(0.0)
Hepatitis B Vaccine	0		1	(0.1)	1	(0.0)
Iron In Combination With Folic Acid, B03ad	0		2	(0.1)	2	(0.1)
Ferrous Fumarate; Folic Acid	0		1	(0.1)	1	(0.0)
Ferrous Sulfate; Folic Acid	0		1	(0.1)	1	(0.0)
Local Anesthetics, C05ad	1	(0.1)	1	(0.1)	2	(0.1)
Lidocaine; Tribenoside	1	(0.1)	1	(0.1)	2	(0.1)
Measles Vaccines, J07bd	0		2	(0.1)	2	(0.1)
Measles Vaccine Live; Rubella Vaccine Live	0		1	(0.1)	1	(0.0)
Measles Vaccine; Rubella Vaccine	0		1	(0.1)	1	(0.0)
Mineral Supplements, A12	1	(0.1)	1	(0.1)	2	(0.1)
Mineral Supplements	1	(0.1)	1	(0.1)	2	(0.1)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Oral Rehydration Salt Formulations, A07ca	1	(0.1)	1	(0.1)	2	(0.1)
Ascorbic Acid; Glucose; Potassium; Sodium	0		1	(0.1)	1	(0.0)
Carbohydrates Nos; Glucose; Potassium Chloride; Sodium Chloride; Sodium Citrate	1	(0.1)	0		1	(0.0)
Other Agents Against Amoebiasis And Other Protozoal Diseases, P01ax	1	(0.1)	1	(0.1)	2	(0.1)
Atovaquone	1	(0.1)	1	(0.1)	2	(0.1)
Other Anti-Acne Preparations For Topical Use, D10ax	1	(0.1)	1	(0.1)	2	(0.1)
Acetone; Acid Fuchsin; Boric Acid; Ethanol; Phenol; Resorcinol	0		1	(0.1)	1	(0.0)
Azelaic Acid	1	(0.1)	0		1	(0.0)
Other Anti-Dementia Drugs, N06dx	0		2	(0.1)	2	(0.1)
Memantine Hydrochloride	0		2	(0.1)	2	(0.1)
Other Antiemetics, A04ad	2	(0.1)	0		2	(0.1)
Aprepitant	2	(0.1)	0		2	(0.1)
Other Antifungals For Topical Use, D01ae	1	(0.1)	1	(0.1)	2	(0.1)
Fenticlor	0		1	(0.1)	1	(0.0)
Tolnaftate	1	(0.1)	0		1	(0.0)
Other Antiinfectives, S01ax	0		2	(0.1)	2	(0.1)
Iodine; Polyvinyl Alcohol	0		1	(0.1)	1	(0.0)
Picloxydine	0		1	(0.1)	1	(0.0)
Other Antiinflammatory/Antirheumatic Agents In Combination With Other Drugs, M01bx	2	(0.1)	0		2	(0.1)
Aceclofenac; Paracetamol; Serrapeptase	2	(0.1)	0		2	(0.1)
Other Antipsoriatics For Topical Use, D05ax	0		2	(0.1)	2	(0.1)
Betamethasone Dipropionate; Calcipotriol	0		1	(0.1)	1	(0.0)
Calcipotriol	0		1	(0.1)	1	(0.0)
Calcipotriol Monohydrate	0		1	(0.1)	1	(0.0)
Other Antithrombotic Agents, B01ax	2	(0.1)	0		2	(0.1)
Fondaparinux	1	(0.1)	0		1	(0.0)
Fondaparinux Sodium	1	(0.1)	0		1	(0.0)
Other Nervous System Drugs, N07xx	1	(0.1)	1	(0.1)	2	(0.1)
Gabapentin Enacarbil	0		1	(0.1)	1	(0.0)
Ginkgo Biloba; Nicotinic Acid; Pantothenic Acid; Pyridoxine Hydrochloride; Riboflavin; Selenium; Thioctic Acid; Vitamin B1 Nos; Vitamin E Nos	1	(0.1)	0		1	(0.0)
Other Quaternary Ammonium Compounds, M03ac	0		2	(0.1)	2	(0.1)
Rocuronium Bromide	0		2	(0.1)	2	(0.1)
Protein Supplements, V06b	2	(0.1)	0		2	(0.1)
Carbohydrates Nos; Lipids Nos; Minerals Nos; Proteins Nos	1	(0.1)	0		1	(0.0)
Soy Protein	1	(0.1)	0		1	(0.0)
Rabies Vaccines, J07bg	0		2	(0.1)	2	(0.1)
Rabies Vaccine	0		1	(0.1)	1	(0.0)
Rabies Vaccine Inact (Chick Embryo)	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Soft Paraffin And Fat Products, D02ac	1	(0.1)	1	(0.1)	2	(0.1)
Petrolatum	1	(0.1)	0		1	(0.0)
White Soft Paraffin	0		1	(0.1)	1	(0.0)
Specific Immunoglobulins, J06bb	0		2	(0.1)	2	(0.1)
Immunoglobulin Equine Anti-Rabies	0		1	(0.1)	1	(0.0)
Immunoglobulin Human Anti-Tetanus	0		1	(0.1)	1	(0.0)
Sympathomimetics In Glaucoma Therapy, S01ea	1	(0.1)	1	(0.1)	2	(0.1)
Apraclonidine Hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Sympathomimetics Used As Decongestants, S01ga	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine Maleate; Chondroitin Sulfate Sodium; Neostigmine Metilsulfate; Potassium Aspartate; Pyridoxine Hydrochloride; Retinol Palmitate; Taurine; Tetryzoline Hydrochloride; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Dipotassium Glycyrrhizate; Pyridoxine Hydrochloride; Tetryzoline Hydrochloride	0		1	(0.1)	1	(0.0)
Chlorphenamine Maleate; Tetryzoline Hydrochloride	0		1	(0.1)	1	(0.0)
Topoisomerase 1 (Top1) Inhibitors, L01ce	2	(0.1)	0		2	(0.1)
Irinotecan	1	(0.1)	0		1	(0.0)
Topotecan Hydrochloride	1	(0.1)	0		1	(0.0)
Triazole Derivatives, J02ac	1	(0.1)	1	(0.1)	2	(0.1)
Itraconazole	1	(0.1)	1	(0.1)	2	(0.1)
Urinary Concrement Solvents, G04bc	0		2	(0.1)	2	(0.1)
Anethole; Borneol; Camphene; Cineole; Fenchone; Pinene	0		1	(0.1)	1	(0.0)
Magnesium Citrate; Potassium Citrate; Pyridoxine Hydrochloride	0		1	(0.1)	1	(0.0)
All Other Therapeutic Products, V03a	0		1	(0.1)	1	(0.0)
Meglumine Sodium Succinate	0		1	(0.1)	1	(0.0)
Amino Acids And Derivatives, A16aa	1	(0.1)	0		1	(0.0)
Levocarnitine Hydrochloride; Tocopheryl Acetate	1	(0.1)	0		1	(0.0)
Amino Acids, Incl. Combinations With Polypeptides, V06dd	1	(0.1)	0		1	(0.0)
Aspartic Acid	1	(0.1)	0		1	(0.0)
Analgesics, N02	0		1	(0.1)	1	(0.0)
Analgesics	0		1	(0.1)	1	(0.0)
Anesthetics, General, N01a	0		1	(0.1)	1	(0.0)
Anesthetics, General	0		1	(0.1)	1	(0.0)
Antacids, Other Combinations, A02ax	1	(0.1)	0		1	(0.0)
Aluminium Silicate; Calcium Carbonate; Cinnamomum Spp. Bark; Citrus Deliciosa Peel; Diastase; Foeniculum Vulgare; Gentiana Lutea Root; Magnesium Carbonate; Myristica Fragrans; Picrasma Quassioides Wood; Sodium	1	(0.1)	0		1	(0.0)
Anti-Androgens, L02bb	1	(0.1)	0		1	(0.0)
Bicalutamide	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Antiarrhythmics, Class Ib, C01bb02	0		1	(0.1)	1	(0.0)
Mexiletine	0		1	(0.1)	1	(0.0)
Antibacterials For Systemic Use, J01	1	(0.1)	0		1	(0.0)
D-Mannose; Lactobacillus Acidophilus	1	(0.1)	0		1	(0.0)
Antiinfectives And Antiseptics For Local Oral Treatment, A01ab	1	(0.1)	0		1	(0.0)
Sodium Perborate Monohydrate	1	(0.1)	0		1	(0.0)
Antivirals For Treatment Of Hcv Infections, J05ap	0		1	(0.1)	1	(0.0)
Sofosbuvir; Velpatasvir	0		1	(0.1)	1	(0.0)
Antivirals, D06bb	1	(0.1)	0		1	(0.0)
Docosanol	1	(0.1)	0		1	(0.0)
Bacterial And Viral Vaccines, Combined, J07ca	1	(0.1)	0		1	(0.0)
Diphtheria Vaccine; Pertussis Vaccine; Polio Vaccine; Tetanus Vaccine	1	(0.1)	0		1	(0.0)
Barbiturates And Derivatives, N03aa	0		1	(0.1)	1	(0.0)
Primidone	0		1	(0.1)	1	(0.0)
Bcr-Abl Tyrosine Kinase Inhibitors, L01ea	1	(0.1)	0		1	(0.0)
Dasatinib Monohydrate	1	(0.1)	0		1	(0.0)
Benzamides, N05al	0		1	(0.1)	1	(0.0)
Amisulpride	0		1	(0.1)	1	(0.0)
Benzomorphan Derivatives, N02ad	0		1	(0.1)	1	(0.0)
Pentazocine	0		1	(0.1)	1	(0.0)
Beta Blocking Agents, Selective, And Thiazides, C07bb	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Metoprolol Succinate	1	(0.1)	0		1	(0.0)
Biguanides, P01bb	1	(0.1)	0		1	(0.0)
Proguanil Hydrochloride	1	(0.1)	0		1	(0.0)
Bile And Liver Therapy, A05	1	(0.1)	0		1	(0.0)
Bicyclol	1	(0.1)	0		1	(0.0)
Bisphosphonates, Combinations, M05bb	1	(0.1)	0		1	(0.0)
Alendronate Sodium; Colecalciferol	1	(0.1)	0		1	(0.0)
Butyrophenone Derivatives, N05ad	1	(0.1)	0		1	(0.0)
Haloperidol	1	(0.1)	0		1	(0.0)
Calcineurin Inhibitors, L04ad	1	(0.1)	0		1	(0.0)
Ciclosporin	1	(0.1)	0		1	(0.0)
Carbohydrates/Proteins/Minerals/Vitamins, Combinations, V06da	0		1	(0.1)	1	(0.0)
Carbohydrates Nos; Minerals Nos; Proteins Nos; Vitamins Nos	0		1	(0.1)	1	(0.0)
Carboxamide Derivatives, N03af01	0		1	(0.1)	1	(0.0)
Carbamazepine	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Caries Prophylactic Agents, A01aa	0		1	(0.1)	1	(0.0)
Calcium Chloride Dihydrate; Magnesium Chloride; Potassium Chloride; Potassium Phosphate Dibasic; Sodium Chloride	0		1	(0.1)	1	(0.0)
Centrally Acting Antiobesity Products, A08aa	1	(0.1)	0		1	(0.0)
Bupropion Hydrochloride; Naltrexone Hydrochloride	1	(0.1)	0		1	(0.0)
Choline Derivatives, M03ab	0		1	(0.1)	1	(0.0)
Suxamethonium Chloride	0		1	(0.1)	1	(0.0)
Choline Esters, N07ab	1	(0.1)	0		1	(0.0)
Bethanechol Chloride	1	(0.1)	0		1	(0.0)
Combinations Of Antineoplastic Agents, L01xy	1	(0.1)	0		1	(0.0)
Fluorouracil; Folinic Acid; Oxaliplatin	1	(0.1)	0		1	(0.0)
Corticosteroids And Antiinfectives In Combination, S03ca	0		1	(0.1)	1	(0.0)
Dexamethasone Sodium Phosphate; Netilmicin Sulfate	0		1	(0.1)	1	(0.0)
Corticosteroids, Plain, D07a	1	(0.1)	0		1	(0.0)
Deprodone Propionate	1	(0.1)	0		1	(0.0)
Corticosteroids, Plain, S01ba	0		1	(0.1)	1	(0.0)
Loteprednol Etabonate	0		1	(0.1)	1	(0.0)
Corticosteroids, Potent, Combinations With Antiseptics, D07bc	1	(0.1)	0		1	(0.0)
Betamethasone Valerate; Clioquinol	1	(0.1)	0		1	(0.0)
Corticosteroids, Very Potent, Other Combinations, D07xd	0		1	(0.1)	1	(0.0)
Clobetasol Propionate; Salicylic Acid	0		1	(0.1)	1	(0.0)
Cosmetics, V07at	0		1	(0.1)	1	(0.0)
Cosmetics	0		1	(0.1)	1	(0.0)
Cyclic Amines, J05ac	1	(0.1)	0		1	(0.0)
Rimantadine Hydrochloride	1	(0.1)	0		1	(0.0)
Emollients And Protectives, D02	1	(0.1)	0		1	(0.0)
Avena Sativa; Beta Glucan; Linum Usitatissimum; Tocopherol; Xylitol	1	(0.1)	0		1	(0.0)
Enemas, A06ag	0		1	(0.1)	1	(0.0)
Glycerol; Polysorbate 80; Sodium Citrate; Sorbitol	0		1	(0.1)	1	(0.0)
Enzymes, M09ab	1	(0.1)	0		1	(0.0)
Amylase; Bromelains; Chymotrypsin; Lipase; Pancreatin; Papain; Rutoside; Trypsin	1	(0.1)	0		1	(0.0)
Ergot Alkaloids, C04ae	0		1	(0.1)	1	(0.0)
Nicergoline	0		1	(0.1)	1	(0.0)
Ergot Alkaloids, N02ca	1	(0.1)	0		1	(0.0)
Caffeine; Cyclizine Hydrochloride; Ergotamine Tartrate	1	(0.1)	0		1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Expectorants, Excl. Combinations With Cough Suppressants, R05c	0		1	(0.1)	1	(0.0)
Ambroxol; Guaifenesin; Levosalbutamol	0		1	(0.1)	1	(0.0)
Fluoroquinolones, S01ae	1	(0.1)	0		1	(0.0)
Besifloxacin Hydrochloride	1	(0.1)	0		1	(0.0)
Gonadotropin Releasing Hormone Analogues, L02ae	1	(0.1)	0		1	(0.0)
Goserelin Acetate	1	(0.1)	0		1	(0.0)
Heparins Or Heparinoids For Topical Use, C05ba	0		1	(0.1)	1	(0.0)
Diethylamine Salicylate; Escin; Heparinoid	0		1	(0.1)	1	(0.0)
High-Ceiling Diuretics And Potassium-Sparing Agents, C03eb	0		1	(0.1)	1	(0.0)
Spironolactone; Torasemide	0		1	(0.1)	1	(0.0)
Imidazole Derivatives, J01xd	1	(0.1)	0		1	(0.0)
Cow Bezoar; Metronidazole	1	(0.1)	0		1	(0.0)
Iodine (125i) Compounds, V09gb	1	(0.1)	0		1	(0.0)
Iodinated (125 I) Human Serum Albumin	1	(0.1)	0		1	(0.0)
Lipid Modifying Agents In Combination With Other Drugs, C10bx	1	(0.1)	0		1	(0.0)
Amlodipine Besilate; Atorvastatin L-Lysine	1	(0.1)	0		1	(0.0)
Low-Ceiling Diuretics And Potassium-Sparing Agents, C03ea	1	(0.1)	0		1	(0.0)
Hydrochlorothiazide; Spironolactone	1	(0.1)	0		1	(0.0)
Medicated Dressings With Antiinfectives, D09aa	0		1	(0.1)	1	(0.0)
Leptospermum Scoparium; Manuka Honey	0		1	(0.1)	1	(0.0)
Nasal Preparations, R01	1	(0.1)	0		1	(0.0)
Nasal Preparations	1	(0.1)	0		1	(0.0)
Nicotinic Acid And Derivatives, C10ad	1	(0.1)	0		1	(0.0)
Nicotinic Acid	1	(0.1)	0		1	(0.0)
Nucleoside And Nucleotide Reverse Transcriptase Inhibitors, J05af	1	(0.1)	0		1	(0.0)
Emtricitabine	1	(0.1)	0		1	(0.0)
Tenofovir Disoproxil	1	(0.1)	0		1	(0.0)
Other Antiallergics, S01gx	1	(0.1)	0		1	(0.0)
Chlorphenamine Maleate; Chondroitin Sulfate Sodium; Cromoglicate Sodium; Dipotassium Glycyrrhizate	1	(0.1)	0		1	(0.0)
Other Antiglaucoma Preparations, S01ex	0		1	(0.1)	1	(0.0)
Ripasudil Hydrochloride Dihydrate	0		1	(0.1)	1	(0.0)
Other Antimigraine Preparations, N02cx	0		1	(0.1)	1	(0.0)
Lomerizine Hydrochloride	0		1	(0.1)	1	(0.0)
Other Antineoplastic Agents, L01xx	0		1	(0.1)	1	(0.0)
Ivosidenib	0		1	(0.1)	1	(0.0)
Other Antipruritics, D04ax	1	(0.1)	0		1	(0.0)
Calamine; Light Liquid Paraffin	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Antiseptics And Disinfectants, D08ax	1	(0.1)	0		1	(0.0)
Ethanol; Methylrosanilinium Chloride	1	(0.1)	0		1	(0.0)
Other Antispasmodics In Combination With Analgesics, A03dc	0		1	(0.1)	1	(0.0)
Metamizole Sodium; Pitofenone Hydrochloride	0		1	(0.1)	1	(0.0)
Other Beta-Lactam Antibacterials, J01d	0		1	(0.1)	1	(0.0)
Cephalosporin Nos	0		1	(0.1)	1	(0.0)
Other Blood Products, B05ax	1	(0.1)	0		1	(0.0)
Red Blood Cells	1	(0.1)	0		1	(0.0)
Other Cephalosporins And Penems, J01di	1	(0.1)	0		1	(0.0)
Faropenem Sodium	1	(0.1)	0		1	(0.0)
Other Dermatologicals, D11ax	0		1	(0.1)	1	(0.0)
Spermidine	0		1	(0.1)	1	(0.0)
Other Diagnostic Agents, V04cx	1	(0.1)	0		1	(0.0)
Urea 13 C	1	(0.1)	0		1	(0.0)
Other Drugs Used In Benign Prostatic Hypertrophy, G04cx	1	(0.1)	0		1	(0.0)
Copper Gluconate; Lycopene; Serenoa Repens; Sitosterol; Zinc Sulfate Monohydrate	1	(0.1)	0		1	(0.0)
Other Drugs Used In Diabetes, A10x	0		1	(0.1)	1	(0.0)
Riboflavin; Rutoside; Thioctic Acid; Vitamin B1 Nos	0		1	(0.1)	1	(0.0)
Other Mineral Products, A12cx	0		1	(0.1)	1	(0.0)
Boron; Calcium Citrate Malate; Copper Sulfate; Magnesium Hydroxide; Manganese Sulfate; Sodium Borate; Zinc Sulfate	0		1	(0.1)	1	(0.0)
Other Mineral Supplements, A12c	1	(0.1)	0		1	(0.0)
Magnesium; Sodium Chloride	1	(0.1)	0		1	(0.0)
Other Plain Vitamin Preparations, A11ha	1	(0.1)	0		1	(0.0)
Biotin	1	(0.1)	0		1	(0.0)
Other Potassium-Sparing Agents, C03db	1	(0.1)	0		1	(0.0)
Amiloride	1	(0.1)	0		1	(0.0)
Other Respiratory System Products, R07ax	0		1	(0.1)	1	(0.0)
Anemarrhena Asphodeloides Rhizome; Calcium Sulfate; Cimicifuga Spp. Rhizome; Eriobotrya Japonica Leaf; Gardenia Jasminoides Fruit; Lilium Spp. Bulb; Magnolia Spp. Flower; Ophiopogon Japonicus Tuber; Scutellar	0		1	(0.1)	1	(0.0)
Other Surgical Aids, S01kx	0		1	(0.1)	1	(0.0)
Calcium Chloride Dihydrate; Glucose; Magnesium Sulfate; Potassium Chloride; Sodium Bicarbonate; Sodium Chloride	0		1	(0.1)	1	(0.0)
Other Systemic Drugs For Obstructive Airway Diseases, R03dx	0		1	(0.1)	1	(0.0)
Suplatast Tosilate	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Other Topical Products For Joint And Muscular Pain, M02ax	0		1	(0.1)	1	(0.0)
Other Topical Products For Joint And Muscular Pain	0		1	(0.1)	1	(0.0)
Otologicals, S02	1	(0.1)	0		1	(0.0)
Otologicals	1	(0.1)	0		1	(0.0)
Paramagnetic Contrast Media, V08ca	0		1	(0.1)	1	(0.0)
Gadoteric Acid	0		1	(0.1)	1	(0.0)
Phenothiazines With Aliphatic Side-Chain, N05aa	1	(0.1)	0		1	(0.0)
Cyamemazine	1	(0.1)	0		1	(0.0)
Phosphodiesterase Inhibitors, C01ce	0		1	(0.1)	1	(0.0)
Milrinone	0		1	(0.1)	1	(0.0)
Polymyxins, J01xb	1	(0.1)	0		1	(0.0)
Polymyxin	1	(0.1)	0		1	(0.0)
Pregnen (4) Derivatives, G03da	1	(0.1)	0		1	(0.0)
Progesterone	1	(0.1)	0		1	(0.0)
Progestogens And Estrogens, Fixed Combinations, G03aa	1	(0.1)	0		1	(0.0)
Desogestrel; Ethinylestradiol	1	(0.1)	0		1	(0.0)
Protease Inhibitors, J05ae	0		1	(0.1)	1	(0.0)
Protease Inhibitors	0		1	(0.1)	1	(0.0)
Pyrimidine Derivatives, C02dc	1	(0.1)	0		1	(0.0)
Minoxidil	1	(0.1)	0		1	(0.0)
Selective Beta-2-Adrenoreceptor Agonists, R03cc	1	(0.1)	0		1	(0.0)
Ambroxol Hydrochloride; Clenbuterol Hydrochloride	1	(0.1)	0		1	(0.0)
Silicone Products, D02aa	0		1	(0.1)	1	(0.0)
Silicon	0		1	(0.1)	1	(0.0)
Softeners, Emollients, A06aa	0		1	(0.1)	1	(0.0)
Magnesium Hydroxide; Paraffin, Liquid; Sodium Picosulfate	0		1	(0.1)	1	(0.0)
Solvents And Diluting Agents, Incl. Irrigating Solutions, V07ab	0		1	(0.1)	1	(0.0)
Water For Injection	0		1	(0.1)	1	(0.0)
Sympathomimetics, Combinations Excl. Corticosteroids, R01ab	1	(0.1)	0		1	(0.0)
Acetylcysteine; Tuaminoheptane Sulfate	1	(0.1)	0		1	(0.0)
Sympathomimetics, Plain, R01aa	0		1	(0.1)	1	(0.0)
Tuaminoheptane	0		1	(0.1)	1	(0.0)
Synthetic Anticholinergic Agents In Combination With Psycholeptics, A03ca	1	(0.1)	0		1	(0.0)
Chlordiazepoxide; Clidinium Bromide; Dicycloverine Hydrochloride	1	(0.1)	0		1	(0.0)
Taxanes, L01cd	0		1	(0.1)	1	(0.0)
Paclitaxel Albumin	0		1	(0.1)	1	(0.0)

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Concomitant medication started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Thiouracils, H03ba	1	(0.1)	0		1	(0.0)
Propylthiouracil	1	(0.1)	0		1	(0.0)
Tumor Necrosis Factor Alpha (Tnf-) Inhibitors, L04ab	0		1	(0.1)	1	(0.0)
Adalimumab	0		1	(0.1)	1	(0.0)
Various, V	1	(0.1)	0		1	(0.0)
Radiotherapy	1	(0.1)	0		1	(0.0)
Vasopressin Antagonists, C03xa	1	(0.1)	0		1	(0.0)
Tolvaptan	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Incl. Combinations, A11e	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Incl. Combinations	1	(0.1)	0		1	(0.0)
Vitamin B-Complex, Other Combinations, A11ex	0		1	(0.1)	1	(0.0)
Bacillus Coagulans; Dexpanthenol; Folic Acid; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin; Thiamine Hydrochloride	0		1	(0.1)	1	(0.0)
Vitamin K, B02ba	0		1	(0.1)	1	(0.0)
Vitamin K Nos	0		1	(0.1)	1	(0.0)
Watersoluble, Nephrotropic, High Osmolar X-Ray Contrast Media, V08aa	0		1	(0.1)	1	(0.0)
Meglumine Amidotrizoate; Sodium Amidotrizoate	0		1	(0.1)	1	(0.0)
Zinc, A12cb	1	(0.1)	0		1	(0.0)
Zinc Citrate	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.28 Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	2170		2170		4340	
All medications	841	(38.8)	854	(39.4)	1695	(39.1)
Vaccine	773	(35.6)	789	(36.4)	1562	(36.0)
Tozinameran	533	(24.6)	512	(23.6)	1045	(24.1)
Elasomeran	153	(7.0)	162	(7.5)	315	(7.3)
Covid-19 vaccine nrvv ad (chadox1 ncov-19)	61	(2.8)	65	(3.0)	126	(2.9)
Covid-19 vaccine	50	(2.3)	46	(2.1)	96	(2.2)
Covid-19 vaccine nrvv ad26 (gam-covid-vac)	26	(1.2)	39	(1.8)	65	(1.5)
Covid-19 vaccine inact (vero)	15	(0.7)	9	(0.4)	24	(0.6)
Covid-19 vaccine inact (vero) hb02	2	(0.1)	14	(0.7)	16	(0.4)
Covid-19 vaccine inact (vero) cz02	5	(0.2)	4	(0.2)	9	(0.2)
Covid-19 vaccine nrvv ad26 (jnj 78436735)	3	(0.1)	3	(0.1)	6	(0.1)
Alendronate sodium	1	(0.1)	1	(0.1)	2	(0.1)
Ciprofloxacin	1	(0.1)	0		1	(0.0)
Covid-19 vaccine inact w.virion aydar-1	1	(0.1)	0		1	(0.0)
Covid-19 vaccine nrvv ad5 (gam-covid-vac)	1	(0.1)	0		1	(0.0)
Covid-19 vaccine prot. Subunit (epivaccorona)	1	(0.1)	0		1	(0.0)
Influenza vaccine	1	(0.1)	0		1	(0.0)
Mvc-cov1901	0		1	(0.1)	1	(0.0)
Treatment	92	(4.2)	94	(4.3)	186	(4.3)
Paracetamol	23	(1.1)	34	(1.6)	57	(1.3)
Dexamethasone	12	(0.6)	8	(0.4)	20	(0.5)
Azithromycin	11	(0.5)	8	(0.4)	19	(0.4)
Ibuprofen	5	(0.2)	12	(0.6)	17	(0.4)
Umifenovir	5	(0.2)	8	(0.4)	13	(0.3)
Acetylsalicylic acid	7	(0.3)	5	(0.2)	12	(0.3)
Acetylcysteine	5	(0.2)	5	(0.2)	10	(0.2)
Favipiravir	8	(0.4)	2	(0.1)	10	(0.2)
Omeprazole	8	(0.4)	1	(0.1)	9	(0.2)
Amoxicillin	2	(0.1)	5	(0.2)	7	(0.2)
Ceftriaxone	5	(0.2)	2	(0.1)	7	(0.2)
Dextromethorphan hydrobromide	3	(0.1)	4	(0.2)	7	(0.2)
Guaifenesin	3	(0.1)	4	(0.2)	7	(0.2)
Prednisone	2	(0.1)	5	(0.2)	7	(0.2)
Apixaban	3	(0.1)	3	(0.1)	6	(0.1)
Levofloxacin	4	(0.2)	2	(0.1)	6	(0.1)
Loratadine	2	(0.1)	4	(0.2)	6	(0.1)
Salbutamol	4	(0.2)	2	(0.1)	6	(0.1)
Amoxicillin; clavulanic acid	0		5	(0.2)	5	(0.1)
Benzonatate	3	(0.1)	2	(0.1)	5	(0.1)
Ceftriaxone sodium	4	(0.2)	1	(0.1)	5	(0.1)
Inosine pranobex	1	(0.1)	4	(0.2)	5	(0.1)
Methylprednisolone	3	(0.1)	2	(0.1)	5	(0.1)
Ambroxol	1	(0.1)	3	(0.1)	4	(0.1)
Ambroxol hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Amoxicillin trihydrate; clavulanate potassium	3	(0.1)	1	(0.1)	4	(0.1)
Dextromethorphan hydrobromide; guaifenesin	1	(0.1)	3	(0.1)	4	(0.1)
Enoxaparin	3	(0.1)	1	(0.1)	4	(0.1)
Enoxaparin sodium	4	(0.2)	0		4	(0.1)
Famotidine	2	(0.1)	2	(0.1)	4	(0.1)
Ivermectin	1	(0.1)	3	(0.1)	4	(0.1)
Oxygen	2	(0.1)	2	(0.1)	4	(0.1)
Phenylephrine	3	(0.1)	1	(0.1)	4	(0.1)
Remdesivir	2	(0.1)	2	(0.1)	4	(0.1)
Rivaroxaban	3	(0.1)	1	(0.1)	4	(0.1)
Budesonide	2	(0.1)	1	(0.1)	3	(0.1)

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Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Casirivimab; imdevimab	2	(0.1)	1	(0.1)	3	(0.1)
Dexamethasone sodium phosphate	2	(0.1)	1	(0.1)	3	(0.1)
Diclofenac	2	(0.1)	1	(0.1)	3	(0.1)
Doxycycline	1	(0.1)	2	(0.1)	3	(0.1)
Erdosteine	1	(0.1)	2	(0.1)	3	(0.1)
Interferon alfa-2b	2	(0.1)	1	(0.1)	3	(0.1)
Olokizumab	3	(0.1)	0		3	(0.1)
Pantoprazole sodium sesquihydrate	2	(0.1)	1	(0.1)	3	(0.1)
Ademetionine	0		2	(0.1)	2	(0.1)
Bamlanivimab	1	(0.1)	1	(0.1)	2	(0.1)
Baricitinib	1	(0.1)	1	(0.1)	2	(0.1)
Bilastine	1	(0.1)	1	(0.1)	2	(0.1)
Bisoprolol	1	(0.1)	1	(0.1)	2	(0.1)
Casirivimab	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine maleate	0		2	(0.1)	2	(0.1)
Ciprofloxacin	1	(0.1)	1	(0.1)	2	(0.1)
Clavulanic acid	1	(0.1)	1	(0.1)	2	(0.1)
Dextromethorphan hydrobromide; promethazine hydrochloride	0		2	(0.1)	2	(0.1)
Furosemide	1	(0.1)	1	(0.1)	2	(0.1)
Heparin	1	(0.1)	1	(0.1)	2	(0.1)
Ibuprofen; paracetamol	0		2	(0.1)	2	(0.1)
Imdevimab	1	(0.1)	1	(0.1)	2	(0.1)
Losartan	1	(0.1)	1	(0.1)	2	(0.1)
Metamizole sodium	1	(0.1)	1	(0.1)	2	(0.1)
Molnupiravir	1	(0.1)	1	(0.1)	2	(0.1)
Nadroparin calcium	2	(0.1)	0		2	(0.1)
Ondansetron	0		2	(0.1)	2	(0.1)
Pantoprazole	0		2	(0.1)	2	(0.1)
Phenylephrine hydrochloride	0		2	(0.1)	2	(0.1)
Pseudoephedrine hydrochloride; triprolidine hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Salbutamol sulfate	1	(0.1)	1	(0.1)	2	(0.1)
Acetylcysteine; tuaminoheptane sulfate	1	(0.1)	0		1	(0.0)
Acetylsalicylic acid; chlorphenamine maleate; phenylephrine bitartrate	0		1	(0.1)	1	(0.0)
Acetylsalicylic acid; magnesium hydroxide	0		1	(0.1)	1	(0.0)
Ambroxol hydrochloride; clenbuterol hydrochloride	1	(0.1)	0		1	(0.0)
Amiodarone	0		1	(0.1)	1	(0.0)
Amlodipine	1	(0.1)	0		1	(0.0)
Ammonium chloride	1	(0.1)	0		1	(0.0)
Antibiotics	0		1	(0.1)	1	(0.0)
Ascorbic acid; codeine phosphate; paracetamol	1	(0.1)	0		1	(0.0)
Ascorbic acid; ibuprofen; pseudoephedrine hydrochloride	1	(0.1)	0		1	(0.0)
Ascorbic acid; paracetamol; phenylephrine hydrochloride	1	(0.1)	0		1	(0.0)
Bamlanivimab; etesevimab	0		1	(0.1)	1	(0.0)
Betamethasone	0		1	(0.1)	1	(0.0)
Betamethasone; dexchlorpheniramine maleate	0		1	(0.1)	1	(0.0)
Bisacodyl	0		1	(0.1)	1	(0.0)
Bradykinin antibodies; histamin antibodies; morphine antibodies	0		1	(0.1)	1	(0.0)
Bromelains	1	(0.1)	0		1	(0.0)
Bromfenac sodium	0		1	(0.1)	1	(0.0)
Bromisoval	0		1	(0.1)	1	(0.0)
Brompheniramine; dextromethorphan; pseudoephedrine	0		1	(0.1)	1	(0.0)
Bumetanide	0		1	(0.1)	1	(0.0)
Butamirate citrate	0		1	(0.1)	1	(0.0)
Captopril	1	(0.1)	0		1	(0.0)
Cefepime	1	(0.1)	0		1	(0.0)
Cefepime hydrochloride; sulbactam sodium	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Cefixime	1	(0.1)	0		1	(0.0)
Cefpodoxime	0		1	(0.1)	1	(0.0)
Cefpodoxime proxetil	1	(0.1)	0		1	(0.0)
Cefprozil	0		1	(0.1)	1	(0.0)
Cefuroxime axetil	1	(0.1)	0		1	(0.0)
Cetirizine	1	(0.1)	0		1	(0.0)
Cetirizine hydrochloride	0		1	(0.1)	1	(0.0)
Chloramphenicol	0		1	(0.1)	1	(0.0)
Chlorhexidine gluconate	1	(0.1)	0		1	(0.0)
Chlorphenamine	1	(0.1)	0		1	(0.0)
Chlorphenamine maleate; dextromethorphan hydrobromide	1	(0.1)	0		1	(0.0)
Chlorphenamine maleate; ibuprofen; pseudoephedrine hydrochloride	0		1	(0.1)	1	(0.0)
Chlorphenamine; dextromethorphan	0		1	(0.1)	1	(0.0)
Chlorphenamine; paracetamol	1	(0.1)	0		1	(0.0)
Choline alfoscerate	1	(0.1)	0		1	(0.0)
Clarithromycin	1	(0.1)	0		1	(0.0)
Clobutinol hydrochloride	1	(0.1)	0		1	(0.0)
Codeine	1	(0.1)	0		1	(0.0)
Codeine phosphate; guaifenesin	0		1	(0.1)	1	(0.0)
Colchicine	1	(0.1)	0		1	(0.0)
Dabigatran etexilate	0		1	(0.1)	1	(0.0)
Dexmedetomidine hydrochloride	0		1	(0.1)	1	(0.0)
Dextromethorphan hydrobromide; doxylamine succinate; ephedrine sulfate; ethanol; paracetamol	0		1	(0.1)	1	(0.0)
Dextromethorphan hydrobromide; guaifenesin; paracetamol	0		1	(0.1)	1	(0.0)
Diclofenac sodium	0		1	(0.1)	1	(0.0)
Digoxin	0		1	(0.1)	1	(0.0)
Dihydrocodeine	0		1	(0.1)	1	(0.0)
Diltiazem	0		1	(0.1)	1	(0.0)
Diltiazem hydrochloride	0		1	(0.1)	1	(0.0)
Dimenhydrinate	0		1	(0.1)	1	(0.0)
Diosmectite	1	(0.1)	0		1	(0.0)
Diphenhydramine	1	(0.1)	0		1	(0.0)
Diphenhydramine salicylate	0		1	(0.1)	1	(0.0)
Diprophylline	0		1	(0.1)	1	(0.0)
Dipyridamole	1	(0.1)	0		1	(0.0)
Docusate sodium	0		1	(0.1)	1	(0.0)
Doxylamine succinate	0		1	(0.1)	1	(0.0)
Dropropizine	0		1	(0.1)	1	(0.0)
Enalapril	0		1	(0.1)	1	(0.0)
Erythromycin	1	(0.1)	0		1	(0.0)
Fenoterol hydrobromide; ipratropium bromide	1	(0.1)	0		1	(0.0)
Fexofenadine hydrochloride; pseudoephedrine hydrochloride	0		1	(0.1)	1	(0.0)
Fluorometholone	0		1	(0.1)	1	(0.0)
Flurbiprofen	0		1	(0.1)	1	(0.0)
Fluticasone	0		1	(0.1)	1	(0.0)
Fluticasone furoate	0		1	(0.1)	1	(0.0)
Fluticasone furoate; vilanterol trifenatate	0		1	(0.1)	1	(0.0)
Fluticasone propionate	1	(0.1)	0		1	(0.0)
Fluticasone; salmeterol	0		1	(0.1)	1	(0.0)
Gemifloxacin mesilate	0		1	(0.1)	1	(0.0)
Glucose	0		1	(0.1)	1	(0.0)
Guaifenesin; terbutaline sulfate	0		1	(0.1)	1	(0.0)
Hexetidine	0		1	(0.1)	1	(0.0)
Homeopathics nos	0		1	(0.1)	1	(0.0)
Hydroxychloroquine	1	(0.1)	0		1	(0.0)
Imidazolyl ethanamide pentandioic acid	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. 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): TR01AG1; criteria: (SAFFL == "Y" & POOLGR2 == "Phase 3a pool")
adcm.xpt; variable(s):CMDECOD C19TTYPE TRAG1 ; criteria: (SCSTT %in% c("AFTER") & POOLGR2 == "Phase 3a pool" & SAFFL == "Y" & C19TTYPE %in% c("TREATMENT", "VACCINE", "PROPHYLACTIC"))
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Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Ipratropium bromide	1	(0.1)	0		1	(0.0)
Ipratropium bromide; levosalbutamol sulfate	0		1	(0.1)	1	(0.0)
Ipratropium bromide; salbutamol sulfate	1	(0.1)	0		1	(0.0)
Ipratropium; salbutamol	0		1	(0.1)	1	(0.0)
Ketoprofen	0		1	(0.1)	1	(0.0)
L-carbocisteine	0		1	(0.1)	1	(0.0)
Levodropropizine	1	(0.1)	0		1	(0.0)
Loperamide	1	(0.1)	0		1	(0.0)
Loxoprofen sodium dihydrate	0		1	(0.1)	1	(0.0)
Magnesium hydroxide	0		1	(0.1)	1	(0.0)
Magnesium sulfate; potassium chloride	0		1	(0.1)	1	(0.0)
Magnesium; sodium chloride	1	(0.1)	0		1	(0.0)
Meglumine sodium succinate	0		1	(0.1)	1	(0.0)
Meldonium	0		1	(0.1)	1	(0.0)
Meropenem	0		1	(0.1)	1	(0.0)
Methylephedrine hydrochloride-dl	0		1	(0.1)	1	(0.0)
Metoclopramide	1	(0.1)	0		1	(0.0)
Metronidazole	1	(0.1)	0		1	(0.0)
Miramistin	0		1	(0.1)	1	(0.0)
Morphine	0		1	(0.1)	1	(0.0)
Moxifloxacin hydrochloride	0		1	(0.1)	1	(0.0)
Moxonidine	1	(0.1)	0		1	(0.0)
Naproxen sodium	1	(0.1)	0		1	(0.0)
Netakimab	0		1	(0.1)	1	(0.0)
Noscapine hydrochloride	0		1	(0.1)	1	(0.0)
Ondansetron hydrochloride	0		1	(0.1)	1	(0.0)
Oseltamivir	1	(0.1)	0		1	(0.0)
Oseltamivir phosphate	1	(0.1)	0		1	(0.0)
Oxyethylammonium methylphenoxyacetate	0		1	(0.1)	1	(0.0)
Paracetamol; pheniramine maleate; phenylephrine hydrochloride	1	(0.1)	0		1	(0.0)
Phenylephrine hydrochloride; tropicamide	1	(0.1)	0		1	(0.0)
Piperacillin; tazobactam	0		1	(0.1)	1	(0.0)
Potassium cresolsulfonate	1	(0.1)	0		1	(0.0)
Potassium phosphate dibasic; potassium phosphate monobasic	0		1	(0.1)	1	(0.0)
Prednisolone	1	(0.1)	0		1	(0.0)
Pregabalin	1	(0.1)	0		1	(0.0)
Promethazine methylene disalicylate	0		1	(0.1)	1	(0.0)
Quetiapine fumarate	1	(0.1)	0		1	(0.0)
Rabeprazole sodium	0		1	(0.1)	1	(0.0)
Riamilovir	0		1	(0.1)	1	(0.0)
Salicylamide	0		1	(0.1)	1	(0.0)
Sodium chloride	0		1	(0.1)	1	(0.0)
Sotrovimab	0		1	(0.1)	1	(0.0)
Spironolactone	0		1	(0.1)	1	(0.0)
Thiamazole	0		1	(0.1)	1	(0.0)
Tiotropium	1	(0.1)	0		1	(0.0)
Tocilizumab	0		1	(0.1)	1	(0.0)
Tofacitinib citrate	1	(0.1)	0		1	(0.0)
Traditional medicine	1	(0.1)	0		1	(0.0)
Tranexamic acid	0		1	(0.1)	1	(0.0)
Vancomycin	1	(0.1)	0		1	(0.0)
Xylometazoline hydrochloride	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Prophylactic	21	(1.0)	24	(1.1)	45	(1.0)
Ascorbic acid	8	(0.4)	10	(0.5)	18	(0.4)
Colecalciferol	5	(0.2)	3	(0.1)	8	(0.2)
Vitamin d nos	4	(0.2)	4	(0.2)	8	(0.2)
Inosine; nicotinamide; riboflavin; succinic acid	1	(0.1)	2	(0.1)	3	(0.1)
Pneumococcal vaccine conj 7v (crm197)	1	(0.1)	2	(0.1)	3	(0.1)
Zinc	2	(0.1)	1	(0.1)	3	(0.1)
Ascorbic acid; zinc	0		2	(0.1)	2	(0.1)
Caffeine	1	(0.1)	1	(0.1)	2	(0.1)
Cyanocobalamin	1	(0.1)	1	(0.1)	2	(0.1)
Pneumococcal vaccine conj 13v (crm197)	1	(0.1)	1	(0.1)	2	(0.1)
Amino acids [umbrella term]	1	(0.1)	0		1	(0.0)
Amino acids nos; glucose; lipids nos	0		1	(0.1)	1	(0.0)
Andrographolide; humic acid; spirulina spp.	1	(0.1)	0		1	(0.0)
Ascorbic acid; betacarotene; bioflavonoids nos; chromium; copper; cystine; folic acid; iodine; iron; levocarnitine; magnesium; manganese; menadione; nicotinic acid; pantothenic acid; pyridoxine hydrochloride; retinol	0		1	(0.1)	1	(0.0)
Ascorbic acid; colecalciferol; selenium; zinc	1	(0.1)	0		1	(0.0)
Bifidobacterium bifidum	1	(0.1)	0		1	(0.0)
Bifidobacterium longum; enterococcus faecium	0		1	(0.1)	1	(0.0)
Cysteine	1	(0.1)	0		1	(0.0)
Ergocalciferol	1	(0.1)	0		1	(0.0)
Eucalyptus globulus oil; pyridoxine hydrochloride; vitamin b1 nos	1	(0.1)	0		1	(0.0)
Famotidine	1	(0.1)	0		1	(0.0)
Homeopathics nos	1	(0.1)	0		1	(0.0)
Hydroxytyrosol; nattokinase	1	(0.1)	0		1	(0.0)
Lactobacillus acidophilus	1	(0.1)	0		1	(0.0)
Lactobacillus helveticus; lactobacillus rhamnosus	1	(0.1)	0		1	(0.0)
Levomenthol; primula spp. Root; thymus spp. Herb	0		1	(0.1)	1	(0.0)
Lysozyme chloride	1	(0.1)	0		1	(0.0)
Multivitamins, plain	0		1	(0.1)	1	(0.0)
Other respiratory system products	0		1	(0.1)	1	(0.0)
Pyridoxine	0		1	(0.1)	1	(0.0)
Thioctic acid	0		1	(0.1)	1	(0.0)
Vitamins nos; zinc sulfate	1	(0.1)	0		1	(0.0)
Vitamins, other combinations	1	(0.1)	0		1	(0.0)
Zinc citrate	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects. Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.1.29 Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	1880		1878		3758	
All medications	722	(38.4)	731	(38.9)	1453	(38.7)
Vaccine	661	(35.2)	675	(35.9)	1336	(35.5)
Tozinameran	455	(24.2)	452	(24.1)	907	(24.1)
Elasomeran	134	(7.1)	128	(6.8)	262	(7.0)
Covid-19 vaccine nrvv ad (chadox1 ncov-19)	59	(3.1)	60	(3.2)	119	(3.2)
Covid-19 vaccine	39	(2.1)	37	(2.0)	76	(2.0)
Covid-19 vaccine nrvv ad26 (gam-covid-vac)	24	(1.3)	31	(1.6)	55	(1.5)
Covid-19 vaccine inact (vero)	15	(0.8)	9	(0.5)	24	(0.6)
Covid-19 vaccine inact (vero) hb02	2	(0.1)	14	(0.8)	16	(0.4)
Covid-19 vaccine inact (vero) cz02	5	(0.3)	4	(0.2)	9	(0.2)
Covid-19 vaccine nrvv ad26 (jnj 78436735)	3	(0.2)	3	(0.2)	6	(0.2)
Alendronate sodium	1	(0.1)	1	(0.1)	2	(0.1)
Ciprofloxacin	1	(0.1)	0		1	(0.0)
Covid-19 vaccine nrvv ad5 (gam-covid-vac)	1	(0.1)	0		1	(0.0)
Covid-19 vaccine prot. Subunit (epivaccorona)	1	(0.1)	0		1	(0.0)
Mvc-cov1901	0		1	(0.1)	1	(0.0)
Treatment	81	(4.3)	78	(4.2)	159	(4.2)
Paracetamol	21	(1.1)	24	(1.3)	45	(1.2)
Azithromycin	10	(0.5)	8	(0.4)	18	(0.5)
Dexamethasone	10	(0.5)	8	(0.4)	18	(0.5)
Ibuprofen	5	(0.3)	11	(0.6)	16	(0.4)
Umifenovir	5	(0.3)	7	(0.4)	12	(0.3)
Acetylsalicylic acid	5	(0.3)	3	(0.2)	8	(0.2)
Favipiravir	6	(0.3)	2	(0.1)	8	(0.2)
Acetylcysteine	3	(0.2)	4	(0.2)	7	(0.2)
Ceftriaxone	5	(0.3)	2	(0.1)	7	(0.2)
Omeprazole	6	(0.3)	1	(0.1)	7	(0.2)
Prednisone	2	(0.1)	5	(0.3)	7	(0.2)
Amoxicillin	2	(0.1)	4	(0.2)	6	(0.2)
Levofloxacin	4	(0.2)	2	(0.1)	6	(0.2)
Loratadine	2	(0.1)	4	(0.2)	6	(0.2)
Apixaban	3	(0.2)	2	(0.1)	5	(0.1)
Benzonatate	3	(0.2)	2	(0.1)	5	(0.1)
Ceftriaxone sodium	4	(0.2)	1	(0.1)	5	(0.1)
Guaifenesin	3	(0.2)	2	(0.1)	5	(0.1)
Inosine pranobex	1	(0.1)	4	(0.2)	5	(0.1)
Salbutamol	3	(0.2)	2	(0.1)	5	(0.1)
Ambroxol hydrochloride	2	(0.1)	2	(0.1)	4	(0.1)
Amoxicillin; clavulanic acid	0		4	(0.2)	4	(0.1)
Dextromethorphan hydrobromide	3	(0.2)	1	(0.1)	4	(0.1)
Enoxaparin	3	(0.2)	1	(0.1)	4	(0.1)
Famotidine	2	(0.1)	2	(0.1)	4	(0.1)
Ivermectin	1	(0.1)	3	(0.2)	4	(0.1)
Methylprednisolone	2	(0.1)	2	(0.1)	4	(0.1)
Oxygen	2	(0.1)	2	(0.1)	4	(0.1)
Phenylephrine	3	(0.2)	1	(0.1)	4	(0.1)
Remdesivir	2	(0.1)	2	(0.1)	4	(0.1)
Rivaroxaban	3	(0.2)	1	(0.1)	4	(0.1)
Ambroxol	1	(0.1)	2	(0.1)	3	(0.1)
Amoxicillin trihydrate; clavulanate potassium	3	(0.2)	0		3	(0.1)
Dexamethasone sodium phosphate	2	(0.1)	1	(0.1)	3	(0.1)
Dextromethorphan hydrobromide; guaifenesin	0		3	(0.2)	3	(0.1)
Diclofenac	2	(0.1)	1	(0.1)	3	(0.1)
Enoxaparin sodium	3	(0.2)	0		3	(0.1)
Olokizumab	3	(0.2)	0		3	(0.1)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Pantoprazole sodium sesquihydrate	2	(0.1)	1	(0.1)	3	(0.1)
Ademetionine	0		2	(0.1)	2	(0.1)
Bamlanivimab	1	(0.1)	1	(0.1)	2	(0.1)
Baricitinib	1	(0.1)	1	(0.1)	2	(0.1)
Bisoprolol	1	(0.1)	1	(0.1)	2	(0.1)
Budesonide	2	(0.1)	0		2	(0.1)
Casirivimab	1	(0.1)	1	(0.1)	2	(0.1)
Casirivimab; imdevimab	1	(0.1)	1	(0.1)	2	(0.1)
Chlorphenamine maleate	0		2	(0.1)	2	(0.1)
Ciprofloxacin	1	(0.1)	1	(0.1)	2	(0.1)
Clavulanic acid	1	(0.1)	1	(0.1)	2	(0.1)
Doxycycline	1	(0.1)	1	(0.1)	2	(0.1)
Erdosteine	1	(0.1)	1	(0.1)	2	(0.1)
Furosemide	1	(0.1)	1	(0.1)	2	(0.1)
Heparin	1	(0.1)	1	(0.1)	2	(0.1)
Ibuprofen; paracetamol	0		2	(0.1)	2	(0.1)
Imdevimab	1	(0.1)	1	(0.1)	2	(0.1)
Interferon alfa-2b	2	(0.1)	0		2	(0.1)
Losartan	1	(0.1)	1	(0.1)	2	(0.1)
Metamizole sodium	1	(0.1)	1	(0.1)	2	(0.1)
Molnupiravir	1	(0.1)	1	(0.1)	2	(0.1)
Nadroparin calcium	2	(0.1)	0		2	(0.1)
Ondansetron	0		2	(0.1)	2	(0.1)
Pseudoephedrine hydrochloride; triprolidine hydrochloride	1	(0.1)	1	(0.1)	2	(0.1)
Salbutamol sulfate	1	(0.1)	1	(0.1)	2	(0.1)
Acetylcysteine; tuaminoheptane sulfate	1	(0.1)	0		1	(0.0)
Acetylsalicylic acid; chlorphenamine maleate; phenylephrine bitartrate	0		1	(0.1)	1	(0.0)
Ambroxol hydrochloride; clenbuterol hydrochloride	1	(0.1)	0		1	(0.0)
Amiodarone	0		1	(0.1)	1	(0.0)
Amlodipine	1	(0.1)	0		1	(0.0)
Ammonium chloride	1	(0.1)	0		1	(0.0)
Antibiotics	0		1	(0.1)	1	(0.0)
Ascorbic acid; paracetamol; phenylephrine hydrochloride	1	(0.1)	0		1	(0.0)
Betamethasone	0		1	(0.1)	1	(0.0)
Betamethasone; dexchlorpheniramine maleate	0		1	(0.1)	1	(0.0)
Bilastine	0		1	(0.1)	1	(0.0)
Bisacodyl	0		1	(0.1)	1	(0.0)
Bradykinin antibodies; histamin antibodies; morphine antibodies	0		1	(0.1)	1	(0.0)
Bromelains	1	(0.1)	0		1	(0.0)
Bromfenac sodium	0		1	(0.1)	1	(0.0)
Bromisoval	0		1	(0.1)	1	(0.0)
Brompheniramine; dextromethorphan; pseudoephedrine	0		1	(0.1)	1	(0.0)
Bumetanide	0		1	(0.1)	1	(0.0)
Butamirate citrate	0		1	(0.1)	1	(0.0)
Captopril	1	(0.1)	0		1	(0.0)
Cefepime	1	(0.1)	0		1	(0.0)
Cefepime hydrochloride; sulbactam sodium	0		1	(0.1)	1	(0.0)
Cefixime	1	(0.1)	0		1	(0.0)
Cefpodoxime	0		1	(0.1)	1	(0.0)
Cefpodoxime proxetil	1	(0.1)	0		1	(0.0)
Cefprozil	0		1	(0.1)	1	(0.0)
Cefuroxime axetil	1	(0.1)	0		1	(0.0)
Cetirizine	1	(0.1)	0		1	(0.0)
Chlorhexidine gluconate	1	(0.1)	0		1	(0.0)
Chlorphenamine	1	(0.1)	0		1	(0.0)
Chlorphenamine maleate; dextromethorphan hydrobromide	1	(0.1)	0		1	(0.0)
Chlorphenamine maleate; ibuprofen; pseudoephedrine	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
hydrochloride						
Chlorphenamine; dextromethorphan	0		1	(0.1)	1	(0.0)
Chlorphenamine; paracetamol	1	(0.1)	0		1	(0.0)
Choline alfoscerate	1	(0.1)	0		1	(0.0)
Clarithromycin	1	(0.1)	0		1	(0.0)
Codeine	1	(0.1)	0		1	(0.0)
Codeine phosphate; guaifenesin	0		1	(0.1)	1	(0.0)
Colchicine	1	(0.1)	0		1	(0.0)
Dabigatran etexilate	0		1	(0.1)	1	(0.0)
Dexmedetomidine hydrochloride	0		1	(0.1)	1	(0.0)
Dextromethorphan hydrobromide; doxylamine succinate; ephedrine sulfate; ethanol; paracetamol	0		1	(0.1)	1	(0.0)
Dextromethorphan hydrobromide; guaifenesin; paracetamol	0		1	(0.1)	1	(0.0)
Dextromethorphan hydrobromide; promethazine hydrochloride	0		1	(0.1)	1	(0.0)
Diclofenac sodium	0		1	(0.1)	1	(0.0)
Digoxin	0		1	(0.1)	1	(0.0)
Dihydrocodeine	0		1	(0.1)	1	(0.0)
Diltiazem	0		1	(0.1)	1	(0.0)
Diltiazem hydrochloride	0		1	(0.1)	1	(0.0)
Dimenhydrinate	0		1	(0.1)	1	(0.0)
Diosmectite	1	(0.1)	0		1	(0.0)
Diphenhydramine	1	(0.1)	0		1	(0.0)
Diphenhydramine salicylate	0		1	(0.1)	1	(0.0)
Diprophylline	0		1	(0.1)	1	(0.0)
Dipyridamole	1	(0.1)	0		1	(0.0)
Docusate sodium	0		1	(0.1)	1	(0.0)
Dropropizine	0		1	(0.1)	1	(0.0)
Enalapril	0		1	(0.1)	1	(0.0)
Erythromycin	1	(0.1)	0		1	(0.0)
Fenoterol hydrobromide; ipratropium bromide	1	(0.1)	0		1	(0.0)
Fexofenadine hydrochloride; pseudoephedrine hydrochloride	0		1	(0.1)	1	(0.0)
Fluorometholone	0		1	(0.1)	1	(0.0)
Flurbiprofen	0		1	(0.1)	1	(0.0)
Fluticasone	0		1	(0.1)	1	(0.0)
Fluticasone furoate; vilanterol trifenatate	0		1	(0.1)	1	(0.0)
Fluticasone; salmeterol	0		1	(0.1)	1	(0.0)
Glucose	0		1	(0.1)	1	(0.0)
Hexetidine	0		1	(0.1)	1	(0.0)
Imidazolyl ethanamide pentandioic acid	1	(0.1)	0		1	(0.0)
Ipratropium bromide	1	(0.1)	0		1	(0.0)
Ipratropium bromide; levosalbutamol sulfate	0		1	(0.1)	1	(0.0)
Ipratropium bromide; salbutamol sulfate	1	(0.1)	0		1	(0.0)
Ipratropium; salbutamol	0		1	(0.1)	1	(0.0)
Ketoprofen	0		1	(0.1)	1	(0.0)
L-carbocisteine	0		1	(0.1)	1	(0.0)
Loperamide	1	(0.1)	0		1	(0.0)
Loxoprofen sodium dihydrate	0		1	(0.1)	1	(0.0)
Magnesium hydroxide	0		1	(0.1)	1	(0.0)
Magnesium sulfate; potassium chloride	0		1	(0.1)	1	(0.0)
Magnesium; sodium chloride	1	(0.1)	0		1	(0.0)
Meglumine sodium succinate	0		1	(0.1)	1	(0.0)
Meldonium	0		1	(0.1)	1	(0.0)
Meropenem	0		1	(0.1)	1	(0.0)
Methylephedrine hydrochloride-dl	0		1	(0.1)	1	(0.0)
Metoclopramide	1	(0.1)	0		1	(0.0)
Metronidazole	1	(0.1)	0		1	(0.0)
Miramistin	0		1	(0.1)	1	(0.0)
Morphine	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Moxifloxacin hydrochloride	0		1	(0.1)	1	(0.0)
Moxonidine	1	(0.1)	0		1	(0.0)
Naproxen sodium	1	(0.1)	0		1	(0.0)
Netakimab	0		1	(0.1)	1	(0.0)
Noscapine hydrochloride	0		1	(0.1)	1	(0.0)
Oseltamivir	1	(0.1)	0		1	(0.0)
Oseltamivir phosphate	1	(0.1)	0		1	(0.0)
Oxyethylammonium methylphenoxyacetate	0		1	(0.1)	1	(0.0)
Pantoprazole	0		1	(0.1)	1	(0.0)
Phenylephrine hydrochloride; tropicamide	1	(0.1)	0		1	(0.0)
Piperacillin; tazobactam	0		1	(0.1)	1	(0.0)
Potassium cresolsulfonate	1	(0.1)	0		1	(0.0)
Potassium phosphate dibasic; potassium phosphate monobasic	0		1	(0.1)	1	(0.0)
Prednisolone	1	(0.1)	0		1	(0.0)
Pregabalin	1	(0.1)	0		1	(0.0)
Promethazine methylene disalicylate	0		1	(0.1)	1	(0.0)
Quetiapine fumarate	1	(0.1)	0		1	(0.0)
Salicylamide	0		1	(0.1)	1	(0.0)
Sodium chloride	0		1	(0.1)	1	(0.0)
Sotrovimab	0		1	(0.1)	1	(0.0)
Spironolactone	0		1	(0.1)	1	(0.0)
Thiamazole	0		1	(0.1)	1	(0.0)
Tiotropium	1	(0.1)	0		1	(0.0)
Tocilizumab	0		1	(0.1)	1	(0.0)
Tofacitinib citrate	1	(0.1)	0		1	(0.0)
Tranexamic acid	0		1	(0.1)	1	(0.0)
Vancomycin	1	(0.1)	0		1	(0.0)
Xylometazoline hydrochloride	0		1	(0.1)	1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Concomitant medication related to COVID-19 treatment, COVID-19 vaccine, or COVID-19 prophylactic started after screening - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Prophylactic	20	(1.1)	20	(1.1)	40	(1.1)
Ascorbic acid	8	(0.4)	7	(0.4)	15	(0.4)
Colecalciferol	5	(0.3)	3	(0.2)	8	(0.2)
Vitamin d nos	4	(0.2)	2	(0.1)	6	(0.2)
Inosine; nicotinamide; riboflavin; succinic acid	1	(0.1)	2	(0.1)	3	(0.1)
Pneumococcal vaccine conj 7v (crm197)	1	(0.1)	2	(0.1)	3	(0.1)
Ascorbic acid; zinc	0		2	(0.1)	2	(0.1)
Caffeine	1	(0.1)	1	(0.1)	2	(0.1)
Cyanocobalamin	1	(0.1)	1	(0.1)	2	(0.1)
Pneumococcal vaccine conj 13v (crm197)	1	(0.1)	1	(0.1)	2	(0.1)
Zinc	2	(0.1)	0		2	(0.1)
Amino acids nos; glucose; lipids nos	0		1	(0.1)	1	(0.0)
Andrographolide; humic acid; spirulina spp.	1	(0.1)	0		1	(0.0)
Ascorbic acid; colecalciferol; selenium; zinc	1	(0.1)	0		1	(0.0)
Bifidobacterium bifidum	1	(0.1)	0		1	(0.0)
Bifidobacterium longum; enterococcus faecium	0		1	(0.1)	1	(0.0)
Cysteine	1	(0.1)	0		1	(0.0)
Ergocalciferol	1	(0.1)	0		1	(0.0)
Eucalyptus globulus oil; pyridoxine hydrochloride; vitamin b1 nos	1	(0.1)	0		1	(0.0)
Famotidine	1	(0.1)	0		1	(0.0)
Hydroxytyrosol; nattokinase	1	(0.1)	0		1	(0.0)
Lactobacillus acidophilus	1	(0.1)	0		1	(0.0)
Lactobacillus helveticus; lactobacillus rhamnosus	1	(0.1)	0		1	(0.0)
Levomenthol; primula spp. Root; thymus spp. Herb	0		1	(0.1)	1	(0.0)
Lysozyme chloride	1	(0.1)	0		1	(0.0)
Multivitamins, plain	0		1	(0.1)	1	(0.0)
Other respiratory system products	0		1	(0.1)	1	(0.0)
Pyridoxine	0		1	(0.1)	1	(0.0)
Thioctic acid	0		1	(0.1)	1	(0.0)
Vitamins nos; zinc sulfate	1	(0.1)	0		1	(0.0)
Vitamins, other combinations	1	(0.1)	0		1	(0.0)
Zinc citrate	1	(0.1)	0		1	(0.0)

%: Percentage of subjects, N: Number of subjects, Generic names of the drugs are presented. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.1.30 Subject disposition and trial conduct outcome related to COVID-19 - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	2170		2170		4340	
Discontinuation of trial product	3	(0.1)	2	(0.1)	5	(0.1)
Individual level	3	(0.1)	2	(0.1)	5	(0.1)
Site level	0		0		0	
Supply disruption	0		0		0	
Withdrawal from trial	0		0		0	
Individual level	0		0		0	
Site level	0		0		0	
Missed primary endpoint ascertainment	4	(0.2)	6	(0.3)	10	(0.2)
Individual level	4	(0.2)	6	(0.3)	10	(0.2)
Site level	0		0		0	
Missed confirmatory secondary endpoint ascertainment	2	(0.1)	2	(0.1)	4	(0.1)
Individual level	2	(0.1)	2	(0.1)	4	(0.1)
Site level	0		0		0	
Use of alternative endpoint ascertainment						
primary endpoint	14	(0.6)	19	(0.9)	33	(0.8)
Remote visit	0		0		0	
Out-of-window visit	14	(0.6)	19	(0.9)	33	(0.8)
confirmatory secondary endpoint	0		2	(0.1)	2	(0.0)
Remote visit	0		0		0	
Out-of-window visit	0		2	(0.1)	2	(0.0)
COVID-19 positive	204	(9.4)	207	(9.5)	411	(9.5)
Serious	24	(1.1)	11	(0.5)	35	(0.8)

%: Percentage of subjects, N: Number of subjects. 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): DCTNAE SEM19FL PEM19FL DCSGR1; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"
adlb.xpt; variable(s): AVISITN PARAMCD ADY; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool" & PARAMCD == "HBA1CB"
adcgmen.xpt; variable(s): PARAMCD; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool" & PARAMCD == "TXIG3910"
adae.xpt; variable(s): AEDECOD AESER; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool" & AEDECOD %in% c("COVID-19", "COVID-19 pneumonia", "Asymptomatic COVID-19", "SARS-CoV-2 test positive")

7.1.31 Subject disposition and trial conduct outcome related to COVID-19 - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	1880		1878		3758	
Discontinuation of trial product	3	(0.2)	2	(0.1)	5	(0.1)
Individual level	3	(0.2)	2	(0.1)	5	(0.1)
Site level	0		0		0	
Supply disruption	0		0		0	
Withdrawal from trial	0		0		0	
Individual level	0		0		0	
Site level	0		0		0	
Missed primary endpoint ascertainment	3	(0.2)	4	(0.2)	7	(0.2)
Individual level	3	(0.2)	4	(0.2)	7	(0.2)
Site level	0		0		0	
Missed confirmatory secondary endpoint ascertainment	2	(0.1)	2	(0.1)	4	(0.1)
Individual level	2	(0.1)	2	(0.1)	4	(0.1)
Site level	0		0		0	
Use of alternative endpoint ascertainment						
primary endpoint	9	(0.5)	16	(0.9)	25	(0.7)
Remote visit	0		0		0	
Out-of-window visit	9	(0.5)	16	(0.9)	25	(0.7)
confirmatory secondary endpoint	0		2	(0.1)	2	(0.1)
Remote visit	0		0		0	
Out-of-window visit	0		2	(0.1)	2	(0.1)
COVID-19 positive	175	(9.3)	171	(9.1)	346	(9.2)
Serious	23	(1.2)	10	(0.5)	33	(0.9)

%: Percentage of subjects, N: Number of subjects, Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): DCTNAE SEM19FL PEM19FL DCSGR1; criteria: SAFFL == "Y" & POOLGR1 == "T2D pool"
adlb.xpt; variable(s): AVISITN PARAMCD ADY; criteria: SAFFL == "Y" & POOLGR1 == "T2D pool" & PARAMCD == "HBA1CB"
adcgmen.xpt; variable(s): PARAMCD; criteria: SAFFL == "Y" & POOLGR1 == "T2D pool" & PARAMCD == "TXIG3910"
adae.xpt; variable(s): AEDECOD AESER; criteria: SAFFL == "Y" & POOLGR1 == "T2D pool" & AEDECOD %in% c("COVID-19", "COVID-19 pneumonia", "Asymptomatic COVID-19", "SARS-CoV-2 test positive")
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:40 - tslcov19sumsas/tslcov19sumt2dsas.txt

7.1.32 Co-participation in COVID-19 trial - summary - safety analysis set - phase 3a pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	2170		2170		4340	
COVID-19 trial co-participation						
Yes	0		0		0	
No	2170	(100.0)	2170	(100.0)	4340	(100.0)

%: Percentage of subjects, N: Number of subjects. COVID-19 trial includes clinical trials with the primary objective of investigating COVID-19 vaccination, treatment and COVID-19 postinfectious conditions of an approved or non-approved investigational medicinal product. COVID-19 trial co-participation is evaluated as anytime during the 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): C19TFL; criteria: SAFFL == "Y" & POOLGR2 == "Phase 3a pool"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:56:33 - tslcov19copartsas/tslcov19copartp3asas.txt

7.1.33 Co-participation in COVID-19 trial - summary - safety analysis set - T2D pool

	Insulin icodec		Daily basal insulin		Total	
	N	(%)	N	(%)	N	(%)
Number of subjects	1880		1878		3758	
COVID-19 trial co-participation						
Yes	0		0		0	
No	1880	(100.0)	1878	(100.0)	3758	(100.0)

%: Percentage of subjects, N: Number of subjects, Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): C19TFL; criteria: SAFFL == "Y" & POOLGR1 == "T2D pool"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:56:35 - tslcov19copartsas/tslcov19copartt2dsas.txt

インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
2. 有害事象

ノボ ノルディスク ファーマ株式会社

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7.2 Adverse events

7.2.1 Adverse events - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	1328	(61.2)	3985	254.67	1263	(58.2)	3878	250.90
Serious								
Yes	166	(7.6)	245	14.82	169	(7.8)	238	13.68
No	1287	(59.3)	3740	239.85	1223	(56.3)	3640	237.22
Missing	0				0			
Severity								
Severe	92	(4.2)	121	7.70	89	(4.1)	133	7.32
Moderate	512	(23.6)	931	57.09	478	(22.0)	856	52.52
Mild	1113	(51.3)	2933	189.88	1073	(49.4)	2889	191.06
Missing	0				0			
Related to basal insulin								
Probable	82	(3.8)	120	8.27	76	(3.5)	133	8.04
Possible	125	(5.8)	179	12.41	105	(4.8)	178	12.49
Unlikely	1276	(58.8)	3674	233.12	1226	(56.5)	3561	229.99
Missing	8	(0.4)	12	0.87	6	(0.3)	6	0.37
Related to technical complaint for basal insulin								
Yes	11	(0.5)	11	0.87	7	(0.3)	8	0.64
No	1325	(61.1)	3961	252.84	1258	(58.0)	3862	249.73
NA	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Missing	8	(0.4)	12	0.87	7	(0.3)	7	0.45
Outcome								
Fatal	14	(0.6)	18	1.17	13	(0.6)	15	0.81
Not recovered/not resolved	589	(27.1)	1087	67.66	570	(26.3)	1042	65.31
Recovered/resolved with sequelae	10	(0.5)	10	0.53	16	(0.7)	18	1.10
Recovering/resolving	96	(4.4)	136	9.08	92	(4.2)	111	7.34
Recovered/resolved	1122	(51.7)	2733	176.18	1039	(47.9)	2690	176.24
Unknown	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Missing	0				0			

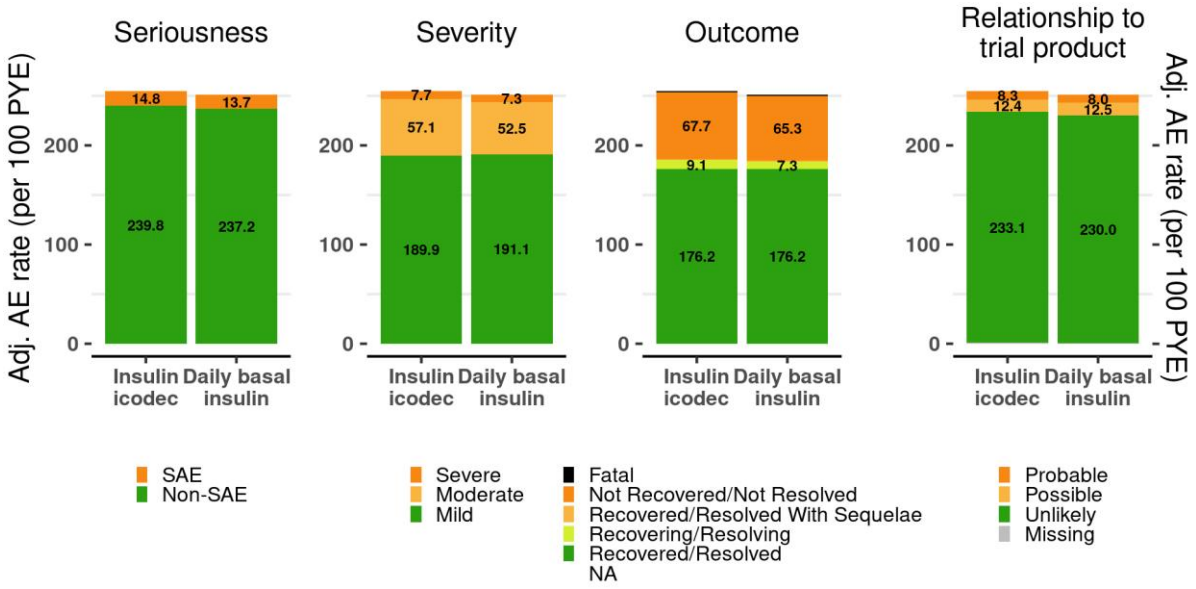
%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, NA: Not applicable, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). Adj.: Adjusted percentages and rates were calculated 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.

7.2.2 Adverse events - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	1139	(60.6)	3478	238.93	1073	(57.1)	3259	223.24
Serious								
Yes	155	(8.2)	230	15.48	162	(8.6)	229	14.83
No	1102	(58.6)	3248	223.45	1036	(55.2)	3030	208.40
Missing	0				0			
Severity								
Severe	83	(4.4)	111	7.81	85	(4.5)	128	7.92
Moderate	461	(24.5)	841	56.13	427	(22.7)	767	51.09
Mild	944	(50.2)	2526	174.99	903	(48.1)	2364	164.23
Missing	0				0			
Related to basal insulin								
Probable	65	(3.5)	100	7.37	69	(3.7)	125	8.43
Possible	103	(5.5)	153	11.50	88	(4.7)	137	10.02
Unlikely	1098	(58.4)	3213	219.06	1037	(55.2)	2991	204.36
Missing	8	(0.4)	12	1.01	6	(0.3)	6	0.43
Related to technical complaint for basal insulin								
Yes	11	(0.6)	11	1.01	7	(0.4)	8	0.74
No	1136	(60.4)	3454	236.83	1068	(56.9)	3243	221.88
NA	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Missing	8	(0.4)	12	1.01	7	(0.4)	7	0.52
Outcome								
Fatal	13	(0.7)	17	1.25	13	(0.7)	15	0.94
Not recovered/not resolved	503	(26.8)	953	63.56	487	(25.9)	898	59.95
Recovered/resolved with sequelae	10	(0.5)	10	0.61	13	(0.7)	15	0.95
Recovering/resolving	90	(4.8)	130	9.83	87	(4.6)	103	7.62
Recovered/resolved	962	(51.2)	2367	163.64	878	(46.7)	2226	153.68
Unknown	1	(0.1)	1	0.05	2	(0.1)	2	0.10
Missing	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.

7.2.3 Adverse events - on-treatment/main-on-treatment - overview plot - safety analysis set - phase 3a pool

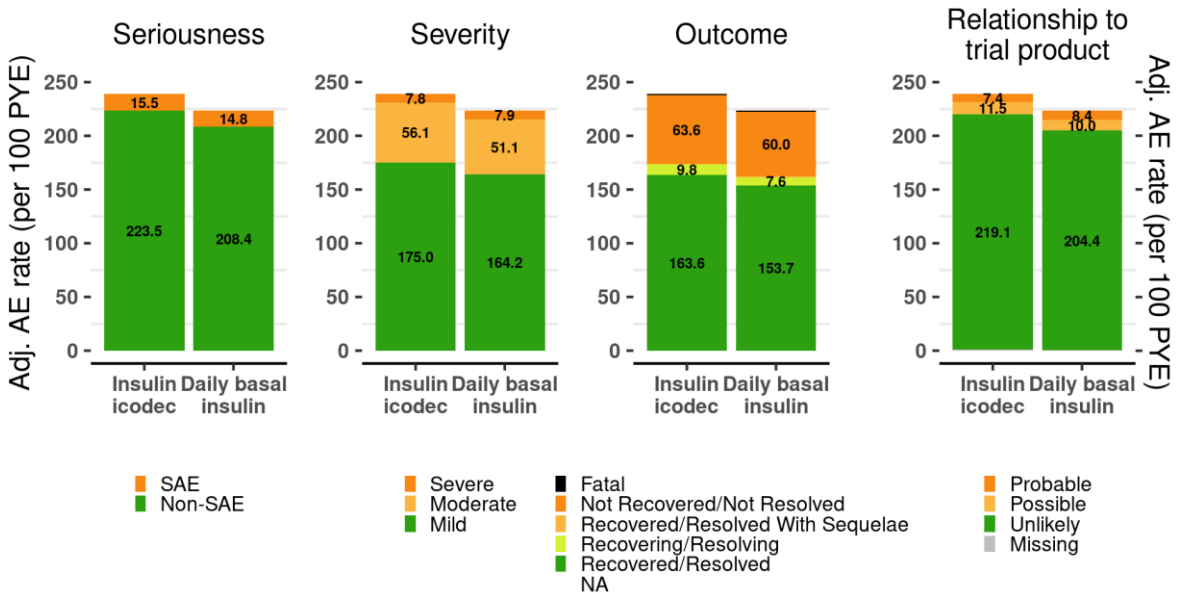


AE rate: Rate (number of adverse events per 100 patient years of exposure). Adj.: Adjusted rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. Event rates <5.0 are shown in bar plots but numbers are not displayed. Daily basal 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; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

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7.2.4 Adverse events - on-treatment/main-on-treatment - overview plot - safety analysis set - T2D pool



AE rate: Rate (number of adverse events per 100 patient years of exposure), Adj.: Adjusted rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. Safety analysis set. Event rates <5.0 are shown in bar plots but numbers are not displayed. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & (ANL06FL) == "Y"

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7.2.5 Adverse events by system organ class and preferred term - most frequent [>=5%] - on-treatment/main- 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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	284	(13.1)	326	22.00	292	(13.5)	334	21.91
Infections and infestations								
COVID-19	181	(8.3)	185	11.92	192	(8.9)	199	12.26
Nasopharyngitis	117	(5.4)	141	10.08	115	(5.3)	135	9.65

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

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7.2.6 Adverse events by system organ class and preferred term - most frequent [>=5%] - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	152	(8.1)	155	10.50	160	(8.5)	165	10.51
Infections and infestations								
COVID-19	152	(8.1)	155	10.50	160	(8.5)	165	10.51

%: 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.

7.2.7 Adverse events by system organ class and preferred term - most frequent [>=1%] - on-treatment/main- 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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	792	(36.5)	1425	93.75	764	(35.2)	1337	88.10
Infections and infestations								
COVID-19	181	(8.3)	185	11.92	192	(8.9)	199	12.26
Nasopharyngitis	117	(5.4)	141	10.08	115	(5.3)	135	9.65
Upper respiratory tract infection	68	(3.1)	81	4.86	52	(2.4)	56	3.54
Urinary tract infection	43	(2.0)	46	3.05	50	(2.3)	56	3.41
Gastroenteritis	32	(1.5)	33	2.45	18	(0.8)	19	1.34
Bronchitis	30	(1.4)	31	2.05	19	(0.9)	19	1.20
Influenza	29	(1.3)	32	2.34	33	(1.5)	36	2.69
Gastrointestinal disorders								
Diarrhoea	89	(4.1)	108	6.65	55	(2.5)	57	3.70
Nausea	41	(1.9)	42	2.58	35	(1.6)	37	2.47
Vomiting	31	(1.4)	39	2.79	21	(1.0)	24	1.55
Nervous system disorders								
Headache	70	(3.2)	92	6.52	64	(2.9)	80	5.30
Dizziness	40	(1.8)	51	3.18	39	(1.8)	47	3.07
Musculoskeletal and connective tissue disorders								
Back pain	65	(3.0)	69	4.18	72	(3.3)	89	6.32
Arthralgia	51	(2.4)	59	3.67	57	(2.6)	63	4.16
Pain in extremity	37	(1.7)	39	2.31	37	(1.7)	43	2.90
Muscle spasms	25	(1.2)	27	1.79	9	(0.4)	9	0.52
Osteoarthritis	24	(1.1)	26	1.58	26	(1.2)	29	1.77
Eye disorders								
Diabetic retinopathy	64	(3.0)	70	5.14	72	(3.3)	76	5.44
Cataract	28	(1.3)	33	1.97	27	(1.2)	30	1.83
General disorders and administration site conditions								
Pyrexia	41	(1.9)	43	2.86	43	(2.0)	45	2.87
Fatigue	32	(1.5)	36	2.31	16	(0.7)	16	0.91
Vascular disorders								
Hypertension	37	(1.7)	37	2.37	38	(1.8)	43	2.71

%: 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 system organ class and preferred term - most frequent [>=1%] - on-treatment/main-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, thoracic and mediastinal disorders								
Cough	26	(1.2)	29	1.87	28	(1.3)	30	2.04
Oropharyngeal pain	24	(1.1)	26	1.60	19	(0.9)	21	1.41
Injury, poisoning and procedural complications								
Vaccination complication	20	(0.9)	24	1.64	29	(1.3)	38	2.55
Metabolism and nutrition disorders								
Hypoglycaemia	18	(0.8)	26	1.97	23	(1.1)	40	2.51

%: 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.

7.2.8 Adverse events by system organ class and preferred term - most frequent [>=1%] - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	709	(37.7)	1292	90.61	675	(35.9)	1166	81.16
Infections and infestations								
COVID-19	152	(8.1)	155	10.50	160	(8.5)	165	10.51
Nasopharyngitis	83	(4.4)	99	7.07	79	(4.2)	92	6.52
Upper respiratory tract infection	62	(3.3)	75	4.96	45	(2.4)	48	3.23
Urinary tract infection	37	(2.0)	40	2.87	44	(2.3)	48	3.08
Influenza	28	(1.5)	31	2.60	28	(1.5)	31	2.57
Gastroenteritis	26	(1.4)	26	2.07	16	(0.9)	17	1.33
Bronchitis	26	(1.4)	27	1.93	17	(0.9)	17	1.17
Gastrointestinal disorders								
Diarrhoea	84	(4.5)	102	7.03	51	(2.7)	52	3.74
Nausea	37	(2.0)	38	2.55	27	(1.4)	29	1.99
Vomiting	24	(1.3)	32	2.46	16	(0.9)	19	1.25
Musculoskeletal and connective tissue disorders								
Back pain	62	(3.3)	66	4.50	61	(3.2)	64	4.61
Arthralgia	45	(2.4)	53	3.59	48	(2.6)	54	3.83
Pain in extremity	31	(1.6)	33	2.01	31	(1.6)	37	2.70
Muscle spasms	23	(1.2)	25	1.85	9	(0.5)	9	0.60
Osteoarthritis	21	(1.1)	23	1.50	24	(1.3)	27	1.82
Nervous system disorders								
Headache	57	(3.0)	73	5.46	54	(2.9)	67	4.72
Dizziness	38	(2.0)	48	3.35	37	(2.0)	44	3.22
Eye disorders								
Diabetic retinopathy	52	(2.8)	58	4.63	58	(3.1)	62	4.78
Cataract	24	(1.3)	29	1.84	25	(1.3)	28	1.90
General disorders and administration site conditions								
Pyrexia	32	(1.7)	33	2.22	37	(2.0)	39	2.67
Fatigue	27	(1.4)	30	2.02	15	(0.8)	15	0.94
Vascular disorders								
Hypertension	32	(1.7)	32	2.19	35	(1.9)	40	2.81

%: 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 system organ class and preferred term - most frequent [>=1%] - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Respiratory, thoracic and mediastinal disorders								
Cough	23	(1.2)	24	1.62	20	(1.1)	21	1.39
Oropharyngeal pain	19	(1.0)	21	1.31	16	(0.9)	18	1.31
Metabolism and nutrition disorders								
Dyslipidaemia	21	(1.1)	22	1.56	17	(0.9)	17	1.33
Hypoglycaemia	13	(0.7)	19	1.51	20	(1.1)	36	2.46
Blood and lymphatic system disorders								
Anaemia	19	(1.0)	21	1.53	14	(0.7)	14	0.94
Investigations								
Weight increased	19	(1.0)	19	1.32	18	(1.0)	18	1.24
Injury, poisoning and procedural complications								
Fall	19	(1.0)	19	1.22	10	(0.5)	11	0.73
Vaccination complication	15	(0.8)	19	1.35	21	(1.1)	27	1.76

%: 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.

7.2.9 Adverse events by system organ class and preferred term - most frequent [>=1%] reported in same or greater proportion of subjects on insulin icodec vs on daily basal insulin - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	476	(21.9)	779	51.15	401	(18.5)	593	39.38
Infections and infestations								
Nasopharyngitis	117	(5.4)	141	10.08	115	(5.3)	135	9.65
Upper respiratory tract infection	68	(3.1)	81	4.86	52	(2.4)	56	3.54
Gastroenteritis	32	(1.5)	33	2.45	18	(0.8)	19	1.34
Bronchitis	30	(1.4)	31	2.05	19	(0.9)	19	1.20
Gastrointestinal disorders								
Diarrhoea	89	(4.1)	108	6.65	55	(2.5)	57	3.70
Nausea	41	(1.9)	42	2.58	35	(1.6)	37	2.47
Vomiting	31	(1.4)	39	2.79	21	(1.0)	24	1.55
Nervous system disorders								
Headache	70	(3.2)	92	6.52	64	(2.9)	80	5.30
Dizziness	40	(1.8)	51	3.18	39	(1.8)	47	3.07
Musculoskeletal and connective tissue disorders								
Pain in extremity	37	(1.7)	39	2.31	37	(1.7)	43	2.90
Muscle spasms	25	(1.2)	27	1.79	9	(0.4)	9	0.52
General disorders and administration site conditions								
Fatigue	32	(1.5)	36	2.31	16	(0.7)	16	0.91
Eye disorders								
Cataract	28	(1.3)	33	1.97	27	(1.2)	30	1.83
Respiratory, thoracic and mediastinal disorders								
Oropharyngeal pain	24	(1.1)	26	1.60	19	(0.9)	21	1.41

%: 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.

7.2.10 Adverse events by system organ class and preferred term - most frequent [>=1%] reported in same or greater proportion of subjects on insulin icodec vs on daily basal insulin - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	484	(25.8)	798	56.40	397	(21.1)	603	42.84
Gastrointestinal disorders								
Diarrhoea	84	(4.5)	102	7.03	51	(2.7)	52	3.74
Nausea	37	(2.0)	38	2.55	27	(1.4)	29	1.99
Vomiting	24	(1.3)	32	2.46	16	(0.9)	19	1.25
Infections and infestations								
Nasopharyngitis	83	(4.4)	99	7.07	79	(4.2)	92	6.52
Upper respiratory tract infection	62	(3.3)	75	4.96	45	(2.4)	48	3.23
Influenza	28	(1.5)	31	2.60	28	(1.5)	31	2.57
Gastroenteritis	26	(1.4)	26	2.07	16	(0.9)	17	1.33
Bronchitis	26	(1.4)	27	1.93	17	(0.9)	17	1.17
Musculoskeletal and connective tissue disorders								
Back pain	62	(3.3)	66	4.50	61	(3.2)	64	4.61
Muscle spasms	23	(1.2)	25	1.85	9	(0.5)	9	0.60
Nervous system disorders								
Headache	57	(3.0)	73	5.46	54	(2.9)	67	4.72
Dizziness	38	(2.0)	48	3.35	37	(2.0)	44	3.22
General disorders and administration site conditions								
Fatigue	27	(1.4)	30	2.02	15	(0.8)	15	0.94
Respiratory, thoracic and mediastinal disorders								
Cough	23	(1.2)	24	1.62	20	(1.1)	21	1.39
Oropharyngeal pain	19	(1.0)	21	1.31	16	(0.9)	18	1.31
Metabolism and nutrition disorders								
Dyslipidaemia	21	(1.1)	22	1.56	17	(0.9)	17	1.33
Blood and lymphatic system disorders								
Anaemia	19	(1.0)	21	1.53	14	(0.7)	14	0.94

%: 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 system organ class and preferred term - most frequent [>=1%] reported in same or greater proportion of subjects on insulin icodec vs on daily basal insulin - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Investigations								
Weight increased	19	(1.0)	19	1.32	18	(1.0)	18	1.24
Injury, poisoning and procedural complications								
Fall	19	(1.0)	19	1.22	10	(0.5)	11	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.

7.2.11 Adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	1328	(61.2)	3985	254.67	1263	(58.2)	3878	250.90
Infections and infestations	648	(29.9)	920	60.38	624	(28.8)	905	57.96
COVID-19	181	(8.3)	185	11.92	192	(8.9)	199	12.26
Nasopharyngitis	117	(5.4)	141	10.08	115	(5.3)	135	9.65
Upper respiratory tract infection	68	(3.1)	81	4.86	52	(2.4)	56	3.54
Urinary tract infection	43	(2.0)	46	3.05	50	(2.3)	56	3.41
Gastroenteritis	32	(1.5)	33	2.45	18	(0.8)	19	1.34
Bronchitis	30	(1.4)	31	2.05	19	(0.9)	19	1.20
Influenza	29	(1.3)	32	2.34	33	(1.5)	36	2.69
Pharyngitis	21	(1.0)	23	1.44	18	(0.8)	21	1.29
Sinusitis	19	(0.9)	21	1.41	19	(0.9)	22	1.34
Cystitis	15	(0.7)	16	1.08	17	(0.8)	19	1.16
Pneumonia	15	(0.7)	15	0.97	6	(0.3)	6	0.37
COVID-19 pneumonia	15	(0.7)	15	0.94	11	(0.5)	11	0.65
Respiratory tract infection viral	12	(0.6)	13	0.98	10	(0.5)	11	0.84
Conjunctivitis	12	(0.6)	12	0.81	7	(0.3)	7	0.42
Herpes zoster	11	(0.5)	11	0.62	17	(0.8)	18	1.05
Tooth abscess	9	(0.4)	9	0.65	7	(0.3)	8	0.47
Rhinitis	9	(0.4)	9	0.55	11	(0.5)	14	1.05
Respiratory tract infection	9	(0.4)	9	0.56	6	(0.3)	6	0.35
Tooth infection	9	(0.4)	11	0.68	8	(0.4)	8	0.57
Otitis media	7	(0.3)	7	0.48	5	(0.2)	5	0.34
Viral infection	7	(0.3)	7	0.44	13	(0.6)	16	0.95
Fungal infection	7	(0.3)	8	0.50	2	(0.1)	2	0.13
Gastroenteritis viral	6	(0.3)	6	0.36	6	(0.3)	6	0.40
Lower respiratory tract infection	6	(0.3)	6	0.33	3	(0.1)	5	0.28
Vaginal infection	6	(0.3)	7	0.51	3	(0.1)	3	0.17
Periodontitis	5	(0.2)	5	0.35	7	(0.3)	7	0.47
Acute sinusitis	5	(0.2)	5	0.26	6	(0.3)	6	0.45
Tonsillitis	4	(0.2)	4	0.26	2	(0.1)	2	0.13
Ear infection	4	(0.2)	4	0.22	5	(0.2)	5	0.29
Cellulitis	4	(0.2)	4	0.21	8	(0.4)	9	0.58
Coronavirus infection	4	(0.2)	4	0.18	5	(0.2)	7	0.44
Gastrointestinal infection	3	(0.1)	3	0.25	5	(0.2)	7	0.46
Gingivitis	3	(0.1)	4	0.23	5	(0.2)	5	0.38
Hordeolum	3	(0.1)	3	0.19	4	(0.2)	4	0.30
Vulvovaginal candidiasis	3	(0.1)	4	0.22	4	(0.2)	4	0.19
Fungal skin infection	3	(0.1)	3	0.22	1	(0.0)	1	0.08
Localised infection	3	(0.1)	3	0.17	3	(0.1)	3	0.22
Wound infection	3	(0.1)	3	0.20	1	(0.0)	1	0.08
Erysipelas	3	(0.1)	3	0.17	2	(0.1)	3	0.20
Respiratory syncytial virus infection	3	(0.1)	3	0.17	0			
Laryngitis	3	(0.1)	3	0.14	5	(0.2)	5	0.35
Genital infection	3	(0.1)	3	0.17	1	(0.0)	1	0.08
Abscess limb	2	(0.1)	2	0.17	2	(0.1)	3	0.27
Vulvitis	2	(0.1)	2	0.17	0			
Tinea pedis	2	(0.1)	2	0.17	2	(0.1)	2	0.17
Genital infection fungal	2	(0.1)	3	0.24	2	(0.1)	2	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. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Onychomycosis	2	(0.1)	2	0.12	4	(0.2)	4	0.18
Oral herpes	2	(0.1)	3	0.24	2	(0.1)	2	0.09
Sepsis	2	(0.1)	2	0.16	1	(0.0)	1	0.05
Furuncle	2	(0.1)	3	0.17	2	(0.1)	2	0.09
Skin infection	2	(0.1)	2	0.13	3	(0.1)	3	0.27
Tinea infection	2	(0.1)	2	0.13	0			
Abscess	2	(0.1)	2	0.13	1	(0.0)	1	0.04
Osteomyelitis	2	(0.1)	2	0.13	0			
Vulvovaginal mycotic infection	2	(0.1)	2	0.13	0			
Candida infection	2	(0.1)	2	0.09	1	(0.0)	1	0.08
Tinea cruris	2	(0.1)	2	0.14	0			
Helicobacter infection	2	(0.1)	2	0.12	2	(0.1)	2	0.13
Subcutaneous abscess	2	(0.1)	2	0.12	2	(0.1)	3	0.14
Otitis externa	2	(0.1)	2	0.12	6	(0.3)	6	0.41
Paronychia	2	(0.1)	2	0.12	2	(0.1)	3	0.24
Acarodermatitis	2	(0.1)	2	0.09	4	(0.2)	4	0.18
Breast abscess	1	(0.0)	1	0.09	3	(0.1)	3	0.17
Eye infection	1	(0.0)	1	0.09	3	(0.1)	3	0.24
Norovirus infection	1	(0.0)	1	0.09	0			
Severe acute respiratory syndrome	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Vulvovaginitis	1	(0.0)	1	0.09	0			
Anal abscess	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Enteritis infectious	1	(0.0)	1	0.08	0			
Kidney infection	1	(0.0)	1	0.08	0			
Paraspinal abscess	1	(0.0)	1	0.08	0			
Pulpitis dental	1	(0.0)	1	0.08	4	(0.2)	4	0.29
Pustule	1	(0.0)	1	0.08	0			
Tinea versicolour	1	(0.0)	1	0.08	0			
Varicella zoster virus infection	1	(0.0)	1	0.08	0			
Escherichia bacteraemia	1	(0.0)	1	0.08	0			
Genital candidiasis	1	(0.0)	1	0.08	0			
Injection site abscess	1	(0.0)	1	0.08	0			
Oral candidiasis	1	(0.0)	1	0.08	0			
Postoperative wound infection	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Suspected COVID-19	1	(0.0)	1	0.08	0			
Bacteraemia	1	(0.0)	1	0.08	0			
Cholecystitis infective	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Diabetic foot infection	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Infected dermal cyst	1	(0.0)	1	0.08	0			
Pharyngotonsillitis	1	(0.0)	1	0.08	2	(0.1)	3	0.14
Pneumonia viral	1	(0.0)	1	0.08	0			
Pulmonary tuberculoma	1	(0.0)	1	0.08	0			
Viral tracheitis	1	(0.0)	1	0.08	0			
Asymptomatic COVID-19	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Bacterial infection	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Balanitis candida	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Chlamydial infection	1	(0.0)	1	0.05	0			
Chronic tonsillitis	1	(0.0)	1	0.05	2	(0.1)	2	0.09
Dermatophytosis of nail	1	(0.0)	1	0.05	2	(0.1)	2	0.09
Escherichia urinary tract infection	1	(0.0)	1	0.05	0			
Folliculitis	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Helicobacter gastritis	1	(0.0)	1	0.05	0			
Herpes simplex	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Herpes virus infection	1	(0.0)	1	0.05	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 system organ class and preferred term - on-treatment/main-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 bite	1	(0.0)	1	0.05	0			
Laryngopharyngitis	1	(0.0)	1	0.05	1	(0.0)	2	0.09
Mastitis	1	(0.0)	1	0.05	0			
Oropharyngeal candidiasis	1	(0.0)	1	0.05	0			
Otitis media chronic	1	(0.0)	1	0.05	0			
Pericoronitis	1	(0.0)	1	0.05	0			
Purulence	1	(0.0)	1	0.05	0			
Tracheitis	1	(0.0)	1	0.05	0			
Urethritis	1	(0.0)	1	0.05	0			
Viral upper respiratory tract infection	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Appendicitis	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Chronic sinusitis	1	(0.0)	1	0.04	3	(0.1)	3	0.14
Clostridium difficile colitis	1	(0.0)	1	0.04	0			
Clostridium difficile infection	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Ear infection fungal	1	(0.0)	1	0.04	0			
Gangrene	1	(0.0)	1	0.04	0			
Nail infection	1	(0.0)	2	0.09	1	(0.0)	1	0.05
Peritonsillar abscess	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Post-acute COVID-19 syndrome	1	(0.0)	2	0.09	0			
Pyelonephritis	1	(0.0)	1	0.04	0			
Skin candida	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Viral pharyngitis	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Diverticulitis	0				5	(0.2)	5	0.23
Otitis media acute	0				3	(0.1)	3	0.17
Urosepsis	0				2	(0.1)	2	0.12
Post procedural infection	0				2	(0.1)	2	0.13
Soft tissue infection	0				2	(0.1)	2	0.16
Abdominal abscess	0				1	(0.0)	1	0.04
Herpes zoster infection neurological	0				1	(0.0)	1	0.04
Sinusitis bacterial	0				1	(0.0)	1	0.04
Sweat gland infection	0				1	(0.0)	1	0.04
Viral rhinitis	0				1	(0.0)	1	0.08
Body tinea	0				1	(0.0)	1	0.05
Breast cellulitis	0				1	(0.0)	1	0.05
Chronic hepatitis C	0				1	(0.0)	1	0.05
Empyema	0				1	(0.0)	1	0.05
Endophthalmitis	0				1	(0.0)	1	0.05
Epididymitis	0				1	(0.0)	1	0.05
Eye infection bacterial	0				1	(0.0)	1	0.05
Fungal balanitis	0				1	(0.0)	1	0.05
Gastroenteritis norovirus	0				1	(0.0)	1	0.05
Giardiasis	0				1	(0.0)	1	0.05
Herpes dermatitis	0				1	(0.0)	1	0.05
Labyrinthitis	0				1	(0.0)	1	0.05
Lyme disease	0				1	(0.0)	1	0.05
Oophoritis	0				1	(0.0)	1	0.05
Parotitis	0				1	(0.0)	1	0.05
Peri-implantitis	0				1	(0.0)	1	0.05
Rotavirus infection	0				1	(0.0)	1	0.05
Salpingitis	0				1	(0.0)	1	0.05
Skin bacterial infection	0				1	(0.0)	1	0.05
Varicella	0				1	(0.0)	1	0.05
Bartholinitis	0				1	(0.0)	1	0.08
Infective iritis	0				1	(0.0)	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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Campylobacter gastroenteritis	0				1	(0.0)	1	0.08
Cystitis escherichia	0				1	(0.0)	1	0.09
Gastric infection	0				1	(0.0)	1	0.09
Infected cyst	0				1	(0.0)	1	0.09
Gastrointestinal disorders	277	(12.8)	418	25.85	245	(11.3)	343	22.03
Diarrhoea	89	(4.1)	108	6.65	55	(2.5)	57	3.70
Nausea	41	(1.9)	42	2.58	35	(1.6)	37	2.47
Vomiting	31	(1.4)	39	2.79	21	(1.0)	24	1.55
Constipation	17	(0.8)	20	1.29	16	(0.7)	16	1.04
Abdominal pain	17	(0.8)	17	1.02	18	(0.8)	19	1.18
Abdominal pain upper	16	(0.7)	18	1.16	16	(0.7)	17	0.99
Toothache	15	(0.7)	15	0.86	13	(0.6)	18	1.43
Gastrooesophageal reflux disease	14	(0.6)	14	0.82	15	(0.7)	15	0.94
Dental caries	12	(0.6)	14	0.69	10	(0.5)	10	0.66
Chronic gastritis	9	(0.4)	9	0.59	6	(0.3)	6	0.41
Dyspepsia	8	(0.4)	8	0.54	9	(0.4)	9	0.56
Abdominal distension	8	(0.4)	8	0.45	5	(0.2)	5	0.34
Gastritis	8	(0.4)	8	0.54	9	(0.4)	9	0.54
Haemorrhoids	7	(0.3)	7	0.39	4	(0.2)	4	0.30
Food poisoning	5	(0.2)	5	0.29	4	(0.2)	5	0.36
Flatulence	4	(0.2)	4	0.25	2	(0.1)	2	0.16
Abdominal discomfort	4	(0.2)	4	0.27	6	(0.3)	7	0.47
Abdominal pain lower	4	(0.2)	4	0.25	2	(0.1)	2	0.09
Diverticulum intestinal	4	(0.2)	4	0.23	1	(0.0)	1	0.04
Large intestine polyp	4	(0.2)	4	0.21	6	(0.3)	7	0.35
Enterocolitis	3	(0.1)	4	0.19	0			
Hypoaesthesia oral	3	(0.1)	5	0.36	0			
Pancreatic failure	2	(0.1)	2	0.17	0			
Hyperaesthesia teeth	2	(0.1)	2	0.12	0			
Gastric polyps	2	(0.1)	2	0.13	4	(0.2)	4	0.31
Anal fissure	2	(0.1)	2	0.14	2	(0.1)	2	0.09
Impaired gastric emptying	2	(0.1)	3	0.23	0			
Hiatus hernia	2	(0.1)	2	0.12	2	(0.1)	2	0.14
Dry mouth	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Rectal polyp	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Aphthous ulcer	2	(0.1)	2	0.09	0			
Inguinal hernia	2	(0.1)	2	0.09	1	(0.0)	2	0.09
Faeces soft	1	(0.0)	1	0.09	0			
Irritable bowel syndrome	1	(0.0)	1	0.09	1	(0.0)	1	0.05
Diverticulum	1	(0.0)	1	0.08	3	(0.1)	3	0.17
Gastrointestinal angiodysplasia	1	(0.0)	1	0.08	0			
Gingival bleeding	1	(0.0)	1	0.08	0			
Intra-abdominal haematoma	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Tongue rough	1	(0.0)	1	0.08	0			
Gastric dilatation	1	(0.0)	1	0.08	0			
Noninfective gingivitis	1	(0.0)	1	0.08	0			
Oral pain	1	(0.0)	1	0.08	0			
Vomiting projectile	1	(0.0)	1	0.08	0			
Pancreatic duct dilatation	1	(0.0)	1	0.08	0			
Pancreatitis chronic	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Proctalgia	1	(0.0)	1	0.08	0			
Anal pruritus	1	(0.0)	1	0.05	0			
Colitis	1	(0.0)	1	0.05	2	(0.1)	2	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Colitis ischaemic	1	(0.0)	1	0.05	0			
Frequent bowel movements	1	(0.0)	1	0.05	0			
Haematochezia	1	(0.0)	1	0.05	0			
Loose tooth	1	(0.0)	1	0.05	0			
Oral discomfort	1	(0.0)	1	0.05	0			
Pancreatitis	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Periodontal disease	1	(0.0)	1	0.05	2	(0.1)	2	0.16
Tooth disorder	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Tooth impacted	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Abdominal wall disorder	1	(0.0)	1	0.04	0			
Colitis microscopic	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Diabetic gastropathy	1	(0.0)	1	0.04	0			
Eosinophilic oesophagitis	1	(0.0)	1	0.04	0			
Eructation	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Gastric ulcer	1	(0.0)	1	0.04	0			
Gastrointestinal haemorrhage	1	(0.0)	1	0.04	2	(0.1)	2	0.12
Haemorrhoidal haemorrhage	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Intestinal dilatation	1	(0.0)	1	0.04	0			
Lip swelling	1	(0.0)	1	0.04	0			
Umbilical hernia	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Ileus	0				2	(0.1)	2	0.09
Acid peptic disease	0				2	(0.1)	2	0.09
Stomatitis	0				2	(0.1)	2	0.09
Odynophagia	0				2	(0.1)	2	0.17
Gastritis erosive	0				2	(0.1)	2	0.19
Mesenteric panniculitis	0				1	(0.0)	1	0.04
Oesophageal pain	0				1	(0.0)	1	0.04
Peptic ulcer	0				1	(0.0)	1	0.04
Small intestinal obstruction	0				1	(0.0)	1	0.04
Faeces pale	0				1	(0.0)	1	0.08
Gastrointestinal disorder	0				1	(0.0)	1	0.08
Gingival disorder	0				1	(0.0)	1	0.08
Upper gastrointestinal haemorrhage	0				1	(0.0)	1	0.08
Crohn's disease	0				1	(0.0)	1	0.05
Duodenitis	0				1	(0.0)	1	0.05
Enteritis	0				1	(0.0)	1	0.05
Epigastric discomfort	0				1	(0.0)	1	0.05
Gastric disorder	0				1	(0.0)	1	0.05
Gastrointestinal inflammation	0				1	(0.0)	1	0.05
Hyperchlorhydria	0				1	(0.0)	1	0.05
Melaena	0				1	(0.0)	1	0.05
Pancreatitis acute	0				1	(0.0)	1	0.05
Periodontal inflammation	0				1	(0.0)	2	0.09
Rectal prolapse	0				1	(0.0)	1	0.05
Ulcerative gastritis	0				1	(0.0)	1	0.05
Gastrointestinal sounds abnormal	0				1	(0.0)	1	0.08
Oesophagitis	0				1	(0.0)	1	0.08
Gastric dysplasia	0				1	(0.0)	1	0.08
Gastric mucosal hypertrophy	0				1	(0.0)	1	0.08
Pancreatic pseudocyst	0				1	(0.0)	1	0.08
Gingival recession	0				1	(0.0)	2	0.19
Lumbar hernia	0				1	(0.0)	1	0.09
Pneumatosis intestinalis	0				1	(0.0)	1	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Musculoskeletal and connective tissue disorders	273	(12.6)	400	24.49	284	(13.1)	401	25.93
Back pain	65	(3.0)	69	4.18	72	(3.3)	89	6.32
Arthralgia	51	(2.4)	59	3.67	57	(2.6)	63	4.16
Pain in extremity	37	(1.7)	39	2.31	37	(1.7)	43	2.90
Muscle spasms	25	(1.2)	27	1.79	9	(0.4)	9	0.52
Osteoarthritis	24	(1.1)	26	1.58	26	(1.2)	29	1.77
Myalgia	16	(0.7)	16	1.09	16	(0.7)	17	1.32
Neck pain	16	(0.7)	16	1.02	8	(0.4)	8	0.44
Trigger finger	9	(0.4)	9	0.68	6	(0.3)	8	0.45
Periarthritis	8	(0.4)	8	0.44	9	(0.4)	9	0.59
Intervertebral disc protrusion	8	(0.4)	12	0.61	6	(0.3)	7	0.39
Tendonitis	8	(0.4)	10	0.58	5	(0.2)	5	0.35
Arthritis	7	(0.3)	7	0.43	6	(0.3)	6	0.41
Spinal osteoarthritis	6	(0.3)	6	0.34	5	(0.2)	6	0.27
Musculoskeletal stiffness	5	(0.2)	5	0.34	2	(0.1)	2	0.14
Rotator cuff syndrome	5	(0.2)	5	0.30	4	(0.2)	4	0.18
Spinal stenosis	4	(0.2)	6	0.41	2	(0.1)	2	0.09
Muscular weakness	4	(0.2)	4	0.30	3	(0.1)	3	0.20
Plantar fasciitis	4	(0.2)	5	0.26	3	(0.1)	3	0.14
Bursitis	4	(0.2)	4	0.21	4	(0.2)	4	0.23
Synovial cyst	3	(0.1)	3	0.19	1	(0.0)	1	0.04
Intervertebral disc disorder	3	(0.1)	3	0.17	2	(0.1)	2	0.13
Tendon disorder	3	(0.1)	3	0.20	1	(0.0)	1	0.08
Musculoskeletal chest pain	3	(0.1)	3	0.14	2	(0.1)	2	0.09
Exostosis	3	(0.1)	3	0.14	1	(0.0)	1	0.05
Foot deformity	3	(0.1)	5	0.26	3	(0.1)	3	0.20
Osteoporosis	2	(0.1)	2	0.16	0			
Tenosynovitis	2	(0.1)	2	0.14	9	(0.4)	10	0.53
Musculoskeletal pain	2	(0.1)	2	0.13	1	(0.0)	1	0.05
Back disorder	2	(0.1)	2	0.13	0			
Coccydynia	2	(0.1)	2	0.13	1	(0.0)	1	0.04
Fibromyalgia	2	(0.1)	2	0.09	0			
Groin pain	2	(0.1)	2	0.09	2	(0.1)	2	0.14
Joint effusion	2	(0.1)	3	0.20	2	(0.1)	2	0.09
Osteochondrosis	2	(0.1)	2	0.12	4	(0.2)	4	0.25
Chondropathy	2	(0.1)	2	0.09	0			
Polyarthritis	2	(0.1)	2	0.09	0			
Limb discomfort	1	(0.0)	1	0.09	0			
Axillary mass	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Flank pain	1	(0.0)	1	0.08	6	(0.3)	7	0.42
Polymyalgia rheumatica	1	(0.0)	1	0.08	1	(0.0)	3	0.24
Soft tissue swelling	1	(0.0)	3	0.23	0			
Arthropathy	1	(0.0)	1	0.08	0			
Muscle contracture	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Pain in jaw	1	(0.0)	1	0.08	0			
Torticollis	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Bone cyst	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Costochondritis	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Fistula	1	(0.0)	1	0.05	0			
Lumbar spinal stenosis	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Myositis	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Osteopenia	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Spinal pain	1	(0.0)	1	0.05	4	(0.2)	4	0.22

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Adverse events by system organ class and preferred term - on-treatment/main-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 claw toe	1	(0.0)	1	0.04	0			
Diastasis recti abdominis	1	(0.0)	1	0.04	0			
Facet joint syndrome	1	(0.0)	1	0.04	0			
Meniscopathy	1	(0.0)	1	0.04	0			
Psoriatic arthropathy	1	(0.0)	1	0.04	0			
Sacroiliitis	1	(0.0)	1	0.04	0			
Rheumatoid arthritis	0				4	(0.2)	4	0.31
Joint swelling	0				3	(0.1)	3	0.20
Nodal osteoarthritis	0				2	(0.1)	2	0.14
Dupuytren's contracture	0				2	(0.1)	2	0.09
Haemarthrosis	0				1	(0.0)	1	0.04
Intervertebral disc space narrowing	0				1	(0.0)	2	0.09
Muscle twitching	0				1	(0.0)	1	0.04
Scoliosis	0				1	(0.0)	1	0.04
Spinal retrolisthesis	0				1	(0.0)	2	0.09
Bone pain	0				1	(0.0)	1	0.08
Jaw disorder	0				1	(0.0)	1	0.08
Periostitis	0				1	(0.0)	1	0.08
Cervical spinal stenosis	0				1	(0.0)	1	0.05
Limb deformity	0				1	(0.0)	1	0.05
Mastication disorder	0				1	(0.0)	2	0.09
Tenosynovitis stenosans	0				1	(0.0)	1	0.05
Vertebral osteophyte	0				1	(0.0)	1	0.05
Intervertebral disc degeneration	0				1	(0.0)	1	0.08
Neuropathic arthropathy	0				1	(0.0)	1	0.08
Osteochondritis	0				1	(0.0)	1	0.08
Chondromalacia	0				1	(0.0)	1	0.09
Limb mass	0				1	(0.0)	1	0.09
General disorders and administration site conditions	240	(11.1)	363	24.35	208	(9.6)	344	22.67
Pyrexia	41	(1.9)	43	2.86	43	(2.0)	45	2.87
Fatigue	32	(1.5)	36	2.31	16	(0.7)	16	0.91
Oedema peripheral	19	(0.9)	19	1.23	10	(0.5)	11	0.62
Malaise	16	(0.7)	18	1.10	15	(0.7)	60	5.00
Injection site reaction	15	(0.7)	29	2.23	6	(0.3)	8	0.46
Chest pain	14	(0.6)	14	0.81	7	(0.3)	7	0.41
Pain	13	(0.6)	14	1.02	14	(0.6)	15	0.89
Vaccination site pain	10	(0.5)	12	0.79	9	(0.4)	9	0.63
Asthenia	10	(0.5)	10	0.63	10	(0.5)	10	0.66
Chest discomfort	8	(0.4)	8	0.50	2	(0.1)	2	0.13
Medical device site dermatitis	7	(0.3)	10	0.67	11	(0.5)	18	1.03
Medical device site reaction	7	(0.3)	9	0.66	1	(0.0)	1	0.05
Influenza like illness	7	(0.3)	8	0.61	4	(0.2)	4	0.23
Medical device site bruise	7	(0.3)	9	0.58	1	(0.0)	1	0.05
Hunger	7	(0.3)	8	0.45	3	(0.1)	4	0.31
Medical device site rash	6	(0.3)	6	0.57	8	(0.4)	8	0.73
Medical device site pruritus	5	(0.2)	5	0.31	4	(0.2)	4	0.33
Peripheral swelling	5	(0.2)	6	0.34	4	(0.2)	4	0.25
Medical device site haemorrhage	4	(0.2)	4	0.19	3	(0.1)	3	0.19
Chills	4	(0.2)	4	0.22	1	(0.0)	1	0.05
Injection site pruritus	4	(0.2)	19	1.43	1	(0.0)	1	0.08
Injection site pain	3	(0.1)	3	0.24	13	(0.6)	31	1.67
Injection site erythema	3	(0.1)	5	0.36	4	(0.2)	4	0.19

%: 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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Thirst	3	(0.1)	3	0.21	1	(0.0)	1	0.08
Feeling abnormal	3	(0.1)	5	0.30	1	(0.0)	1	0.05
Injection site bruising	3	(0.1)	3	0.20	5	(0.2)	5	0.26
Drug intolerance	3	(0.1)	3	0.14	0			
Gait disturbance	3	(0.1)	3	0.14	1	(0.0)	1	0.04
Inflammation	2	(0.1)	2	0.17	3	(0.1)	3	0.17
Medical device site erythema	2	(0.1)	2	0.16	5	(0.2)	6	0.50
Injection site swelling	2	(0.1)	2	0.16	1	(0.0)	1	0.08
Medical device site pain	2	(0.1)	2	0.14	3	(0.1)	3	0.22
Injection site haematoma	2	(0.1)	6	0.47	3	(0.1)	8	0.63
Injection site haemorrhage	2	(0.1)	2	0.16	2	(0.1)	2	0.13
Discomfort	2	(0.1)	2	0.13	1	(0.0)	8	0.64
Injection site hypersensitivity	2	(0.1)	2	0.09	0			
Swelling face	2	(0.1)	2	0.14	2	(0.1)	2	0.12
Injection site mass	2	(0.1)	2	0.09	1	(0.0)	1	0.09
Injection site urticaria	1	(0.0)	2	0.19	1	(0.0)	1	0.05
Medical device site haematoma	1	(0.0)	1	0.09	1	(0.0)	1	0.05
Medical device site irritation	1	(0.0)	1	0.09	0			
Application site bruise	1	(0.0)	1	0.08	0			
Application site pruritus	1	(0.0)	1	0.08	0			
Injection site rash	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Oedema	1	(0.0)	1	0.08	3	(0.1)	3	0.17
Oedema due to renal disease	1	(0.0)	1	0.08	0			
Vaccination site inflammation	1	(0.0)	1	0.08	0			
Vaccination site pruritus	1	(0.0)	1	0.08	0			
Xerosis	1	(0.0)	1	0.08	0			
Feeling hot	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Implant site pruritus	1	(0.0)	1	0.05	0			
Injection site dermatitis	1	(0.0)	1	0.05	0			
Medical device site eczema	1	(0.0)	1	0.05	2	(0.1)	2	0.09
Medical device site hypersensitivity	1	(0.0)	1	0.05	0			
Swelling	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Vaccination site reaction	1	(0.0)	1	0.05	0			
Early satiety	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Localised oedema	1	(0.0)	1	0.04	0			
Vessel puncture site bruise	1	(0.0)	1	0.04	0			
Non-cardiac chest pain	0				4	(0.2)	6	0.27
Death	0				3	(0.1)	3	0.14
Cyst	0				2	(0.1)	2	0.12
Injection site induration	0				2	(0.1)	2	0.12
Hernia	0				1	(0.0)	1	0.04
Systemic inflammatory response syndrome	0				1	(0.0)	1	0.04
Axillary pain	0				1	(0.0)	1	0.08
Facial pain	0				1	(0.0)	1	0.08
Injection site hypertrophy	0				1	(0.0)	1	0.05
Medical device site inflammation	0				1	(0.0)	1	0.05
Procedural failure	0				1	(0.0)	1	0.05
Vaccination site erythema	0				1	(0.0)	1	0.05
Injection site oedema	0				1	(0.0)	1	0.08
Condition aggravated	0				1	(0.0)	1	0.08
Hyperthermia	0				1	(0.0)	1	0.09
Nervous system disorders	207	(9.5)	298	19.60	207	(9.5)	326	22.45

%: 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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Headache	70	(3.2)	92	6.52	64	(2.9)	80	5.30
Dizziness	40	(1.8)	51	3.18	39	(1.8)	47	3.07
Sciatica	13	(0.6)	13	0.83	12	(0.6)	13	0.73
Tremor	12	(0.6)	13	0.71	10	(0.5)	61	5.45
Carpal tunnel syndrome	11	(0.5)	11	0.64	8	(0.4)	8	0.55
Hypoaesthesia	9	(0.4)	12	0.72	10	(0.5)	11	0.69
Migraine	8	(0.4)	9	0.65	5	(0.2)	5	0.39
Paraesthesia	8	(0.4)	9	0.44	12	(0.6)	12	0.79
Syncope	7	(0.3)	7	0.41	1	(0.0)	1	0.05
Diabetic neuropathy	6	(0.3)	6	0.42	12	(0.6)	12	0.75
Neuropathy peripheral	6	(0.3)	7	0.46	10	(0.5)	10	0.60
Burning sensation	3	(0.1)	3	0.19	3	(0.1)	3	0.17
Tension headache	3	(0.1)	4	0.22	0			
Transient ischaemic attack	3	(0.1)	3	0.17	3	(0.1)	3	0.17
Dysgeusia	3	(0.1)	3	0.17	0			
Autonomic nervous system imbalance	2	(0.1)	2	0.17	0			
Cervicobrachial syndrome	2	(0.1)	2	0.17	1	(0.0)	1	0.04
Somnolence	2	(0.1)	2	0.17	1	(0.0)	1	0.05
Post herpetic neuralgia	2	(0.1)	2	0.12	1	(0.0)	1	0.09
Cerebrovascular disorder	2	(0.1)	2	0.13	0			
Memory impairment	2	(0.1)	2	0.13	1	(0.0)	1	0.08
Disturbance in attention	2	(0.1)	10	0.89	0			
Neuralgia	2	(0.1)	2	0.12	1	(0.0)	1	0.05
Amnesia	2	(0.1)	2	0.12	0			
Carotid artery stenosis	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Haemorrhage intracranial	1	(0.0)	1	0.09	0			
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Loss of consciousness	1	(0.0)	1	0.09	2	(0.1)	2	0.14
Sinus headache	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Speech disorder	1	(0.0)	1	0.09	0			
Carotid artery aneurysm	1	(0.0)	1	0.08	0			
Facial paralysis	1	(0.0)	1	0.08	0			
Peripheral paralysis	1	(0.0)	1	0.08	0			
Piriformis syndrome	1	(0.0)	1	0.08	0			
Thalamic infarction	1	(0.0)	1	0.08	0			
Vascular headache	1	(0.0)	1	0.08	0			
Cerebral arteriosclerosis	1	(0.0)	1	0.08	0			
Vascular encephalopathy	1	(0.0)	1	0.08	0			
Ageusia	1	(0.0)	1	0.05	0			
Anosmia	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Balance disorder	1	(0.0)	1	0.05	0			
Cerebral haemorrhage	1	(0.0)	1	0.05	0			
Cervical radiculopathy	1	(0.0)	1	0.05	0			
Dizziness postural	1	(0.0)	1	0.05	2	(0.1)	2	0.17
Lumbar radiculopathy	1	(0.0)	1	0.05	4	(0.2)	5	0.23
Neuroglycopenia	1	(0.0)	1	0.05	1	(0.0)	3	0.14
Presyncope	1	(0.0)	1	0.05	4	(0.2)	4	0.18
Trigeminal neuralgia	1	(0.0)	1	0.05	0			
Cerebral atrophy	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Cluster headache	1	(0.0)	1	0.04	0			
Cognitive disorder	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Intracranial pressure increased	1	(0.0)	1	0.04	0			
Cerebrovascular accident	0				2	(0.1)	2	0.12
Lethargy	0				2	(0.1)	2	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. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Thrombotic stroke	0				2	(0.1)	2	0.13
Cerebral artery embolism	0				1	(0.0)	1	0.04
Dementia Alzheimer's type	0				1	(0.0)	1	0.04
Ischaemic stroke	0				1	(0.0)	1	0.04
Ophthalmic migraine	0				1	(0.0)	1	0.04
Orthostatic tremor	0				1	(0.0)	1	0.04
Radiculopathy	0				1	(0.0)	1	0.04
White matter lesion	0				1	(0.0)	1	0.04
Basilar migraine	0				1	(0.0)	1	0.08
Essential tremor	0				1	(0.0)	1	0.08
Facial nerve disorder	0				1	(0.0)	1	0.08
Hemiparesis	0				1	(0.0)	1	0.08
Hypoglycaemic coma	0				1	(0.0)	1	0.08
Hyporeflexia	0				1	(0.0)	1	0.08
Morton's neuralgia	0				1	(0.0)	1	0.08
Sleep deficit	0				1	(0.0)	1	0.08
Brain injury	0				1	(0.0)	1	0.05
Carotid arteriosclerosis	0				1	(0.0)	1	0.05
Mental impairment	0				1	(0.0)	1	0.05
Parkinsonian gait	0				1	(0.0)	1	0.05
Vertebral artery occlusion	0				1	(0.0)	1	0.05
Meralgia paraesthetica	0				1	(0.0)	1	0.08
Myelopathy	0				1	(0.0)	1	0.08
Cerebral infarction	0				1	(0.0)	1	0.08
Restless legs syndrome	0				1	(0.0)	1	0.08
Encephalopathy	0				1	(0.0)	1	0.09
Hypoglycaemic unconsciousness	0				1	(0.0)	1	0.09
Hypotonia	0				1	(0.0)	1	0.09
Injury, poisoning and procedural complications	194	(8.9)	241	15.69	180	(8.3)	217	14.75
Vaccination complication	20	(0.9)	24	1.64	29	(1.3)	38	2.55
Fall	20	(0.9)	20	1.15	11	(0.5)	12	0.72
Contusion	15	(0.7)	16	0.95	9	(0.4)	9	0.54
Accidental overdose	14	(0.6)	15	1.24	4	(0.2)	5	0.41
Ligament sprain	12	(0.6)	12	0.86	8	(0.4)	8	0.53
Skin abrasion	9	(0.4)	12	0.78	5	(0.2)	5	0.38
Hand fracture	7	(0.3)	7	0.47	1	(0.0)	1	0.04
Skin laceration	7	(0.3)	7	0.42	1	(0.0)	1	0.09
Incorrect dose administered	6	(0.3)	6	0.52	5	(0.2)	7	0.52
Limb injury	6	(0.3)	6	0.39	6	(0.3)	7	0.49
Prescribed overdose	5	(0.2)	5	0.47	0			
Joint injury	5	(0.2)	5	0.33	5	(0.2)	5	0.31
Procedural pain	5	(0.2)	5	0.34	1	(0.0)	1	0.08
Road traffic accident	5	(0.2)	6	0.43	1	(0.0)	1	0.04
Overdose	4	(0.2)	4	0.28	3	(0.1)	3	0.21
Rib fracture	4	(0.2)	4	0.25	5	(0.2)	5	0.29
Tooth fracture	4	(0.2)	4	0.25	3	(0.1)	3	0.22
Ankle fracture	4	(0.2)	4	0.18	3	(0.1)	3	0.13
Thermal burn	3	(0.1)	3	0.20	2	(0.1)	2	0.13
Arthropod bite	3	(0.1)	3	0.24	4	(0.2)	4	0.30
Wound	3	(0.1)	3	0.17	6	(0.3)	6	0.46
Foot fracture	3	(0.1)	3	0.20	3	(0.1)	3	0.17
Arthropod sting	3	(0.1)	3	0.17	1	(0.0)	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 system organ class and preferred term - on-treatment/main-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 limb fracture	3	(0.1)	3	0.13	0			
Face injury	2	(0.1)	2	0.17	1	(0.0)	1	0.09
Medication error	2	(0.1)	2	0.16	3	(0.1)	3	0.25
Fibula fracture	2	(0.1)	2	0.09	2	(0.1)	2	0.14
Injury	2	(0.1)	2	0.09	0			
Meniscus injury	2	(0.1)	2	0.09	5	(0.2)	5	0.26
Tendon rupture	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Hip fracture	2	(0.1)	2	0.09	0			
Radius fracture	2	(0.1)	2	0.09	2	(0.1)	2	0.14
Back injury	2	(0.1)	2	0.09	2	(0.1)	2	0.14
Epicondylitis	1	(0.0)	1	0.09	1	(0.0)	1	0.04
Product administration error	1	(0.0)	1	0.09	2	(0.1)	2	0.12
Product dispensing error	1	(0.0)	1	0.09	0			
Craniocerebral injury	1	(0.0)	1	0.08	0			
Facial bones fracture	1	(0.0)	1	0.08	0			
Subcutaneous haematoma	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Underdose	1	(0.0)	1	0.08	5	(0.2)	5	0.36
Wrist fracture	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Gun shot wound	1	(0.0)	1	0.08	0			
Ligament rupture	1	(0.0)	2	0.16	0			
Procedural complication	1	(0.0)	1	0.08	0			
Accidental underdose	1	(0.0)	1	0.08	0			
Chillblains	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Extra dose administered	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Subdural haematoma	1	(0.0)	1	0.08	0			
Wrong product administered	1	(0.0)	2	0.16	6	(0.3)	6	0.53
Burn oral cavity	1	(0.0)	1	0.05	0			
Burns first degree	1	(0.0)	1	0.05	1	(0.0)	1	0.09
Cervical vertebral fracture	1	(0.0)	1	0.05	0			
Eye injury	1	(0.0)	1	0.05	0			
Heat illness	1	(0.0)	1	0.05	3	(0.1)	4	0.22
Muscle strain	1	(0.0)	1	0.05	5	(0.2)	5	0.34
Post procedural fistula	1	(0.0)	1	0.05	0			
Post procedural haemorrhage	1	(0.0)	1	0.05	0			
Post procedural hypothyroidism	1	(0.0)	1	0.05	0			
Scar	1	(0.0)	1	0.05	0			
Traumatic haematoma	1	(0.0)	1	0.05	0			
Animal bite	1	(0.0)	1	0.04	3	(0.1)	3	0.17
Bone contusion	1	(0.0)	1	0.04	2	(0.1)	2	0.13
Femoral neck fracture	1	(0.0)	1	0.04	0			
Inflammation of wound	1	(0.0)	1	0.04	0			
Injury of conjunctiva	1	(0.0)	1	0.04	0			
Multiple injuries	1	(0.0)	1	0.04	0			
Muscle injury	1	(0.0)	1	0.04	2	(0.1)	2	0.16
Neck injury	1	(0.0)	1	0.04	0			
Penile contusion	1	(0.0)	1	0.04	0			
Post procedural complication	1	(0.0)	1	0.04	0			
Post procedural haematuria	1	(0.0)	1	0.04	0			
Post procedural inflammation	1	(0.0)	1	0.04	0			
Radiation skin injury	1	(0.0)	1	0.04	0			
Spinal compression fracture	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Soft tissue injury	0				2	(0.1)	2	0.09
Concussion	0				2	(0.1)	2	0.16
Wrong dose	0				2	(0.1)	2	0.16

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Head injury	0				1	(0.0)	1	0.04
Humerus fracture	0				1	(0.0)	1	0.04
Periprocedural myocardial infarction	0				1	(0.0)	1	0.04
Scratch	0				1	(0.0)	1	0.04
Sunburn	0				1	(0.0)	1	0.04
Crush injury	0				1	(0.0)	1	0.08
Exposure to SARS-CoV-2	0				1	(0.0)	1	0.08
Spinal column injury	0				1	(0.0)	1	0.08
Deafness traumatic	0				1	(0.0)	1	0.05
Endotracheal intubation complication	0				1	(0.0)	1	0.05
Lower limb fracture	0				1	(0.0)	1	0.05
Post procedural stroke	0				1	(0.0)	1	0.05
Post procedural swelling	0				1	(0.0)	2	0.09
Intentional product use issue	0				1	(0.0)	1	0.08
Post-traumatic neck syndrome	0				1	(0.0)	1	0.08
Seroma	0				1	(0.0)	1	0.08
Intentional overdose	0				1	(0.0)	1	0.08
Muscle contusion	0				1	(0.0)	1	0.08
Stab wound	0				1	(0.0)	1	0.08
Tendon injury	0				1	(0.0)	1	0.08
Tibia fracture	0				1	(0.0)	1	0.08
Anaemia postoperative	0				1	(0.0)	1	0.09
Animal scratch	0				1	(0.0)	1	0.09
Clavicle fracture	0				1	(0.0)	1	0.09
Corneal abrasion	0				1	(0.0)	1	0.09
Heat stroke	0				1	(0.0)	1	0.09
Nerve injury	0				1	(0.0)	1	0.09
Wound dehiscence	0				1	(0.0)	1	0.09
Eye disorders	176	(8.1)	225	15.28	180	(8.3)	236	16.31
Diabetic retinopathy	64	(3.0)	70	5.14	72	(3.3)	76	5.44
Cataract	28	(1.3)	33	1.97	27	(1.2)	30	1.83
Macular oedema	12	(0.6)	13	0.99	5	(0.2)	5	0.31
Retinopathy hypertensive	8	(0.4)	9	0.64	5	(0.2)	5	0.37
Dry eye	7	(0.3)	7	0.40	7	(0.3)	7	0.41
Diabetic retinal oedema	6	(0.3)	6	0.50	10	(0.5)	11	0.75
Vision blurred	6	(0.3)	6	0.44	5	(0.2)	5	0.30
Blepharitis	5	(0.2)	5	0.26	0			
Retinal haemorrhage	4	(0.2)	4	0.28	0			
Glaucoma	4	(0.2)	4	0.23	6	(0.3)	6	0.45
Eye pain	4	(0.2)	4	0.21	3	(0.1)	3	0.17
Non-proliferative retinopathy	3	(0.1)	4	0.35	4	(0.2)	4	0.34
Conjunctival haemorrhage	3	(0.1)	3	0.22	0			
Vitreous detachment	3	(0.1)	3	0.17	2	(0.1)	2	0.19
Cataract nuclear	2	(0.1)	2	0.17	0			
Epiretinal membrane	2	(0.1)	2	0.17	3	(0.1)	3	0.22
Ocular hyperaemia	2	(0.1)	3	0.24	1	(0.0)	2	0.16
Posterior capsule opacification	2	(0.1)	2	0.14	0			
Vitreous haemorrhage	2	(0.1)	2	0.16	2	(0.1)	2	0.13
Conjunctivitis allergic	2	(0.1)	3	0.17	0			
Eye inflammation	2	(0.1)	2	0.13	2	(0.1)	2	0.16
Diplopia	2	(0.1)	2	0.13	1	(0.0)	1	0.08
Arteriosclerotic retinopathy	2	(0.1)	2	0.14	0			
Ocular hypertension	2	(0.1)	2	0.12	2	(0.1)	3	0.23

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Adverse events by system organ class and preferred term - on-treatment/main-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	2	(0.1)	2	0.12	0			
Astigmatism	2	(0.1)	3	0.14	5	(0.2)	5	0.34
Corneal erosion	1	(0.0)	1	0.09	1	(0.0)	1	0.08
Retinal vascular disorder	1	(0.0)	1	0.09	1	(0.0)	1	0.08
Dry age-related macular degeneration	1	(0.0)	1	0.08	0			
Eye irritation	1	(0.0)	1	0.08	0			
Lacrimation increased	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Myopia	1	(0.0)	1	0.08	3	(0.1)	3	0.18
Retinal exudates	1	(0.0)	1	0.08	2	(0.1)	2	0.16
Retinal vein occlusion	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Presbyopia	1	(0.0)	1	0.08	3	(0.1)	3	0.25
Retinal deposits	1	(0.0)	1	0.08	0			
Retinal drusen	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Retinal scar	1	(0.0)	1	0.08	0			
Acquired epiblepharon	1	(0.0)	1	0.05	0			
Asthenopia	1	(0.0)	1	0.05	0			
Conjunctival erosion	1	(0.0)	1	0.05	0			
Optic disc vascular disorder	1	(0.0)	1	0.05	0			
Post thrombotic retinopathy	1	(0.0)	1	0.05	0			
Retinal aneurysm	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Retinal tear	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Amaurosis fugax	1	(0.0)	1	0.04	0			
Angle closure glaucoma	1	(0.0)	1	0.04	0			
Conjunctival hyperaemia	1	(0.0)	1	0.04	0			
Conjunctival suffusion	1	(0.0)	1	0.04	0			
Maculopathy	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Retinal degeneration	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Visual impairment	1	(0.0)	1	0.04	2	(0.1)	10	0.77
Vitreous opacities	1	(0.0)	1	0.04	0			
Macular degeneration	0				3	(0.1)	3	0.17
Vitreous floaters	0				3	(0.1)	3	0.27
Retinal artery occlusion	0				2	(0.1)	2	0.09
Eye discharge	0				2	(0.1)	2	0.13
Retinal detachment	0				2	(0.1)	2	0.13
Retinopathy	0				2	(0.1)	2	0.17
Cystoid macular oedema	0				1	(0.0)	1	0.04
Eyelid oedema	0				1	(0.0)	1	0.04
Hypermetropia	0				1	(0.0)	1	0.04
Ocular ischaemic syndrome	0				1	(0.0)	1	0.04
Ophthalmic vein thrombosis	0				1	(0.0)	1	0.04
Meibomianitis	0				1	(0.0)	1	0.08
Open angle glaucoma	0				1	(0.0)	2	0.16
Dacryoadenitis acquired	0				1	(0.0)	1	0.05
Normal tension glaucoma	0				1	(0.0)	1	0.05
Photophobia	0				1	(0.0)	1	0.05
Scintillating scotoma	0				1	(0.0)	1	0.05
Uveitis	0				1	(0.0)	1	0.05
Chorioretinal atrophy	0				1	(0.0)	1	0.08
Corneal bleeding	0				1	(0.0)	1	0.08
Eye pruritus	0				1	(0.0)	2	0.16
Macular hole	0				1	(0.0)	1	0.08
Optic disc haemorrhage	0				1	(0.0)	1	0.08
Vitreous degeneration	0				1	(0.0)	1	0.08
Visual acuity reduced	0				1	(0.0)	1	0.08

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Adverse events by system organ class and preferred term - on-treatment/main-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	0				1	(0.0)	1	0.09
Pterygium	0				1	(0.0)	1	0.09
Respiratory, thoracic and mediastinal disorders	132	(6.1)	177	11.50	122	(5.6)	153	10.09
Cough	26	(1.2)	29	1.87	28	(1.3)	30	2.04
Oropharyngeal pain	24	(1.1)	26	1.60	19	(0.9)	21	1.41
Rhinorrhoea	12	(0.6)	15	1.01	13	(0.6)	13	0.95
Nasal congestion	10	(0.5)	10	0.52	5	(0.2)	5	0.28
Dyspnoea	9	(0.4)	9	0.57	13	(0.6)	14	0.85
Respiratory disorder	8	(0.4)	8	0.66	7	(0.3)	7	0.49
Sleep apnoea syndrome	7	(0.3)	7	0.39	0			
Epistaxis	6	(0.3)	10	0.80	2	(0.1)	4	0.25
Sinus congestion	6	(0.3)	7	0.49	2	(0.1)	2	0.14
Asthma	5	(0.2)	6	0.38	1	(0.0)	1	0.08
Chronic obstructive pulmonary disease	4	(0.2)	4	0.28	1	(0.0)	1	0.05
Productive cough	4	(0.2)	4	0.25	4	(0.2)	4	0.31
Sneezing	3	(0.1)	3	0.22	0			
Acute respiratory failure	3	(0.1)	3	0.17	1	(0.0)	1	0.05
Dyspnoea exertional	2	(0.1)	2	0.14	2	(0.1)	2	0.09
Upper-airway cough syndrome	2	(0.1)	2	0.14	1	(0.0)	1	0.09
Nasal septum deviation	2	(0.1)	2	0.16	1	(0.0)	1	0.08
Emphysema	2	(0.1)	2	0.13	2	(0.1)	2	0.13
Pulmonary fibrosis	2	(0.1)	3	0.17	0			
Sinus pain	2	(0.1)	3	0.17	1	(0.0)	1	0.08
Interstitial lung disease	2	(0.1)	2	0.09	0			
Rhinitis allergic	2	(0.1)	2	0.14	6	(0.3)	10	0.64
Bronchial hyperreactivity	1	(0.0)	1	0.09	0			
Hiccups	1	(0.0)	1	0.09	0			
Pulmonary congestion	1	(0.0)	1	0.09	0			
Nasal obstruction	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Respiratory failure	1	(0.0)	1	0.08	2	(0.1)	2	0.09
Bronchospasm	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Pleurisy	1	(0.0)	1	0.08	1	(0.0)	1	0.09
Pulmonary hypertension	1	(0.0)	1	0.08	0			
Acquired diaphragmatic eventration	1	(0.0)	1	0.05	0			
Bronchiectasis	1	(0.0)	1	0.05	0			
Laryngeal cyst	1	(0.0)	1	0.05	0			
Nasal dryness	1	(0.0)	1	0.05	0			
Nasal turbinate hypertrophy	1	(0.0)	1	0.05	0			
Pulmonary embolism	1	(0.0)	1	0.05	0			
Pulmonary mass	1	(0.0)	1	0.05	4	(0.2)	4	0.25
Throat irritation	1	(0.0)	1	0.05	2	(0.1)	2	0.17
Increased viscosity of upper respiratory secretion	1	(0.0)	1	0.04	0			
Upper respiratory tract inflammation	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Pleural effusion	0				3	(0.1)	3	0.14
Paranasal cyst	0				2	(0.1)	2	0.16
Bronchitis chronic	0				2	(0.1)	2	0.13
Allergic cough	0				2	(0.1)	2	0.17
Aphonia	0				1	(0.0)	1	0.04
Respiratory tract inflammation	0				1	(0.0)	1	0.04
Acute pulmonary oedema	0				1	(0.0)	1	0.05
Allergic bronchitis	0				1	(0.0)	1	0.05

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Haemoptysis	0				1	(0.0)	1	0.05
Paranasal sinus discomfort	0				1	(0.0)	1	0.05
Pleuritic pain	0				1	(0.0)	1	0.05
Dry throat	0				1	(0.0)	1	0.08
Dysphonia	0				1	(0.0)	2	0.16
Lung disorder	0				1	(0.0)	1	0.08
Pleural disorder	0				1	(0.0)	1	0.08
Metabolism and nutrition disorders	132	(6.1)	163	9.63	134	(6.2)	169	10.36
Dyslipidaemia	21	(1.0)	22	1.35	17	(0.8)	17	1.15
Hypoglycaemia	18	(0.8)	26	1.97	23	(1.1)	40	2.51
Vitamin D deficiency	17	(0.8)	17	0.85	14	(0.6)	14	0.80
Hyperlipidaemia	14	(0.6)	14	0.80	13	(0.6)	13	0.72
Vitamin B12 deficiency	11	(0.5)	11	0.49	1	(0.0)	1	0.04
Hypertriglyceridaemia	10	(0.5)	10	0.56	8	(0.4)	8	0.51
Hyperkalaemia	8	(0.4)	9	0.51	10	(0.5)	10	0.63
Hyperglycaemia	6	(0.3)	7	0.48	14	(0.6)	14	0.92
Iron deficiency	5	(0.2)	5	0.22	3	(0.1)	3	0.13
Decreased appetite	4	(0.2)	4	0.22	5	(0.2)	5	0.26
Hyperuricaemia	4	(0.2)	4	0.26	3	(0.1)	3	0.14
Gout	4	(0.2)	5	0.23	6	(0.3)	7	0.32
Hyponatraemia	3	(0.1)	3	0.25	1	(0.0)	1	0.08
Hypercholesterolaemia	3	(0.1)	3	0.21	4	(0.2)	4	0.30
Increased appetite	3	(0.1)	3	0.14	6	(0.3)	7	0.49
Fluid retention	2	(0.1)	2	0.13	0			
Hypokalaemia	2	(0.1)	2	0.13	1	(0.0)	1	0.05
Dehydration	2	(0.1)	2	0.12	2	(0.1)	3	0.23
Zinc deficiency	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Diabetes mellitus	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Folate deficiency	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Abnormal weight gain	1	(0.0)	1	0.08	0			
Hypoalbuminaemia	1	(0.0)	1	0.08	0			
Obesity	1	(0.0)	1	0.05	2	(0.1)	2	0.17
Diabetes mellitus inadequate control	1	(0.0)	1	0.04	0			
Hypernatraemia	1	(0.0)	1	0.04	0			
Magnesium deficiency	1	(0.0)	1	0.04	0			
Malnutrition	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Vitamin B complex deficiency	1	(0.0)	1	0.04	0			
Insulin resistance	0				2	(0.1)	2	0.14
Hypercalcaemia	0				1	(0.0)	1	0.04
Lactic acidosis	0				1	(0.0)	1	0.04
Lipomatosis	0				1	(0.0)	1	0.08
Appetite disorder	0				1	(0.0)	2	0.09
Electrolyte imbalance	0				1	(0.0)	1	0.05
Metabolic disorder	0				1	(0.0)	1	0.05
Food craving	0				1	(0.0)	1	0.08
Metabolic acidosis	0				1	(0.0)	1	0.08
Hyperammonaemia	0				1	(0.0)	1	0.08
Skin and subcutaneous tissue disorders	123	(5.7)	131	8.46	128	(5.9)	155	9.98
Rash	14	(0.6)	14	0.95	11	(0.5)	12	0.62
Eczema	10	(0.5)	10	0.56	7	(0.3)	7	0.50
Alopecia	8	(0.4)	8	0.58	3	(0.1)	3	0.17
Hyperhidrosis	8	(0.4)	8	0.50	5	(0.2)	5	0.30

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pruritus	8	(0.4)	8	0.46	12	(0.6)	12	0.77
Dermatitis	7	(0.3)	7	0.55	7	(0.3)	8	0.51
Dermatitis contact	7	(0.3)	8	0.47	14	(0.6)	14	1.00
Urticaria	7	(0.3)	7	0.45	12	(0.6)	12	0.72
Skin irritation	4	(0.2)	5	0.33	3	(0.1)	3	0.18
Dry skin	4	(0.2)	4	0.23	5	(0.2)	5	0.31
Cold sweat	4	(0.2)	4	0.25	8	(0.4)	12	1.01
Skin ulcer	4	(0.2)	4	0.25	5	(0.2)	5	0.36
Night sweats	3	(0.1)	3	0.17	0			
Blister	2	(0.1)	2	0.17	2	(0.1)	2	0.13
Rash erythematous	2	(0.1)	2	0.17	0			
Miliaria	2	(0.1)	2	0.16	4	(0.2)	4	0.19
Skin lesion	2	(0.1)	2	0.14	2	(0.1)	2	0.14
Hyperkeratosis	2	(0.1)	2	0.13	2	(0.1)	2	0.17
Psoriasis	2	(0.1)	2	0.09	2	(0.1)	2	0.12
Acne	2	(0.1)	2	0.12	0			
Dermatitis allergic	2	(0.1)	2	0.09	1	(0.0)	1	0.08
Ingrowing nail	2	(0.1)	2	0.09	3	(0.1)	3	0.14
Dermal cyst	1	(0.0)	1	0.09	4	(0.2)	4	0.27
Hidradenitis	1	(0.0)	1	0.09	1	(0.0)	1	0.04
Ingrown hair	1	(0.0)	1	0.09	0			
Lichen sclerosus	1	(0.0)	1	0.09	0			
Macule	1	(0.0)	1	0.09	1	(0.0)	1	0.05
Xeroderma	1	(0.0)	1	0.09	0			
Rash papular	1	(0.0)	1	0.08	0			
Decubitus ulcer	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Ecchymosis	1	(0.0)	1	0.08	2	(0.1)	2	0.09
Skin odour abnormal	1	(0.0)	1	0.08	0			
Intertrigo	1	(0.0)	1	0.08	0			
Umbilical haematoma	1	(0.0)	1	0.08	0			
Angioedema	1	(0.0)	1	0.05	3	(0.1)	3	0.18
Granuloma annulare	1	(0.0)	1	0.05	0			
Lipodystrophy acquired	1	(0.0)	1	0.05	0			
Myxoid cyst	1	(0.0)	1	0.05	0			
Skin exfoliation	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Skin fissures	1	(0.0)	1	0.05	0			
Urticaria contact	1	(0.0)	1	0.05	0			
Diabetic foot	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Erythema	1	(0.0)	1	0.04	4	(0.2)	4	0.26
Livedo reticularis	1	(0.0)	1	0.04	0			
Nail bed inflammation	1	(0.0)	1	0.04	0			
Lipohypertrophy	0				2	(0.1)	2	0.13
Dermatitis atopic	0				2	(0.1)	2	0.19
Seborrhoea	0				1	(0.0)	1	0.08
Skin reaction	0				1	(0.0)	1	0.08
Actinic keratosis	0				1	(0.0)	1	0.05
Alopecia areata	0				1	(0.0)	1	0.05
Asteatosis	0				1	(0.0)	1	0.05
Cold urticaria	0				1	(0.0)	1	0.05
Drug eruption	0				1	(0.0)	1	0.05
Haemorrhage subcutaneous	0				1	(0.0)	1	0.05
Lentigo	0				1	(0.0)	1	0.05
Purpura	0				1	(0.0)	1	0.05
Urticaria thermal	0				1	(0.0)	1	0.05

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Leukoplakia	0				1	(0.0)	1	0.08
Pruritus allergic	0				1	(0.0)	1	0.08
Rash maculo-papular	0				1	(0.0)	1	0.08
Skin discolouration	0				1	(0.0)	1	0.08
Neurodermatitis	0				1	(0.0)	1	0.08
Chronic spontaneous urticaria	0				1	(0.0)	1	0.09
Telangiectasia	0				1	(0.0)	1	0.09
Cardiac disorders	95	(4.4)	133	7.44	84	(3.9)	115	6.56
Atrial fibrillation	13	(0.6)	14	0.73	6	(0.3)	6	0.31
Coronary artery disease	12	(0.6)	12	0.61	10	(0.5)	10	0.52
Acute myocardial infarction	9	(0.4)	9	0.51	8	(0.4)	8	0.47
Ventricular extrasystoles	8	(0.4)	8	0.52	2	(0.1)	3	0.14
Cardiac failure	8	(0.4)	8	0.40	3	(0.1)	4	0.30
Palpitations	7	(0.3)	7	0.40	7	(0.3)	7	0.45
Angina pectoris	7	(0.3)	7	0.40	4	(0.2)	4	0.22
Myocardial infarction	6	(0.3)	6	0.38	4	(0.2)	4	0.18
Cardiac failure congestive	4	(0.2)	4	0.22	2	(0.1)	3	0.24
Acute coronary syndrome	4	(0.2)	4	0.18	0			
Supraventricular extrasystoles	3	(0.1)	3	0.20	2	(0.1)	2	0.09
Myocardial ischaemia	3	(0.1)	3	0.21	3	(0.1)	3	0.18
Angina unstable	3	(0.1)	3	0.14	2	(0.1)	2	0.14
Mitral valve incompetence	3	(0.1)	3	0.17	2	(0.1)	2	0.09
Left ventricular hypertrophy	3	(0.1)	3	0.14	2	(0.1)	2	0.13
Tachycardia	3	(0.1)	3	0.13	7	(0.3)	7	0.42
Bundle branch block right	2	(0.1)	2	0.14	7	(0.3)	8	0.48
Left ventricular dysfunction	2	(0.1)	2	0.13	2	(0.1)	2	0.13
Cardiac failure chronic	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Coronary artery occlusion	2	(0.1)	2	0.09	0			
Supraventricular tachycardia	2	(0.1)	2	0.12	0			
Atrioventricular block first degree	2	(0.1)	2	0.12	0			
Bundle branch block left	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Arrhythmia	2	(0.1)	2	0.09	3	(0.1)	3	0.17
Cardiomegaly	1	(0.0)	1	0.09	0			
Cardiovascular disorder	1	(0.0)	1	0.09	0			
Cardiac flutter	1	(0.0)	1	0.08	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Mitral valve stenosis	1	(0.0)	1	0.08	0			
Aortic valve sclerosis	1	(0.0)	1	0.08	0			
Left atrial enlargement	1	(0.0)	1	0.08	2	(0.1)	2	0.12
Aortic valve incompetence	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Atrial flutter	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Atrial thrombosis	1	(0.0)	1	0.05	0			
Bradycardia	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Cardiac ventricular thrombosis	1	(0.0)	1	0.05	0			
Chronic coronary syndrome	1	(0.0)	1	0.05	0			
Diastolic dysfunction	1	(0.0)	1	0.05	0			
Left atrial dilatation	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Pericardial effusion	1	(0.0)	1	0.05	0			
Pericarditis	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Sinus tachycardia	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Tricuspid valve incompetence	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Arteriosclerosis coronary artery	1	(0.0)	1	0.04	0			
Sinus bradycardia	0				3	(0.1)	3	0.17

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac arrest	0				2	(0.1)	2	0.09
Subendocardial ischaemia	0				2	(0.1)	2	0.09
Aortic valve calcification	0				2	(0.1)	2	0.13
Cardiac failure acute	0				1	(0.0)	1	0.04
Coronary artery stenosis	0				1	(0.0)	1	0.04
Ventricular arrhythmia	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrial enlargement	0				1	(0.0)	1	0.08
Cardiac perfusion defect	0				1	(0.0)	2	0.16
Atrioventricular block complete	0				1	(0.0)	1	0.05
Cardiac dysfunction	0				1	(0.0)	1	0.05
Sinus arrhythmia	0				1	(0.0)	1	0.05
Investigations	94	(4.3)	109	7.01	79	(3.6)	88	5.78
Weight increased	20	(0.9)	20	1.23	18	(0.8)	18	1.07
Blood creatinine increased	8	(0.4)	8	0.56	0			
SARS-CoV-2 test positive	7	(0.3)	7	0.49	4	(0.2)	4	0.37
Blood pressure increased	5	(0.2)	5	0.36	4	(0.2)	4	0.22
Alanine aminotransferase increased	4	(0.2)	4	0.28	0			
Blood triglycerides increased	4	(0.2)	4	0.27	3	(0.1)	3	0.14
Weight decreased	4	(0.2)	4	0.18	2	(0.1)	2	0.14
Blood cholesterol increased	3	(0.1)	3	0.19	1	(0.0)	1	0.09
Blood alkaline phosphatase increased	3	(0.1)	3	0.24	0			
Liver function test increased	3	(0.1)	3	0.20	1	(0.0)	1	0.04
Blood immunoglobulin E increased	3	(0.1)	3	0.13	3	(0.1)	3	0.13
Aspartate aminotransferase increased	2	(0.1)	2	0.17	1	(0.0)	1	0.05
Electrocardiogram abnormal	2	(0.1)	2	0.14	2	(0.1)	2	0.12
Hepatic enzyme increased	2	(0.1)	2	0.14	2	(0.1)	2	0.14
Low density lipoprotein increased	2	(0.1)	2	0.14	2	(0.1)	2	0.16
Occult blood	2	(0.1)	2	0.12	0			
Prostatic specific antigen increased	2	(0.1)	2	0.09	0			
Angiogram	1	(0.0)	1	0.09	0			
Blood testosterone decreased	1	(0.0)	1	0.09	0			
Heart rate increased	1	(0.0)	1	0.09	0			
Hepatitis B virus test positive	1	(0.0)	1	0.09	0			
Mycobacterium tuberculosis complex test positive	1	(0.0)	1	0.09	0			
Occult blood positive	1	(0.0)	1	0.09	0			
Arthroscopy	1	(0.0)	1	0.08	0			
Blood glucose fluctuation	1	(0.0)	1	0.08	0			
Blood potassium increased	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Monocyte count decreased	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Monofilament pressure perception test	1	(0.0)	1	0.08	0			
Catheterisation cardiac	1	(0.0)	1	0.08	0			
Eosinophil count increased	1	(0.0)	1	0.08	1	(0.0)	2	0.19
Liver function test abnormal	1	(0.0)	1	0.08	1	(0.0)	2	0.16
Blood creatine increased	1	(0.0)	1	0.05	0			
Blood creatine phosphokinase increased	1	(0.0)	1	0.05	0			
Body temperature increased	1	(0.0)	1	0.05	0			
Glycosylated haemoglobin increased	1	(0.0)	1	0.05	2	(0.1)	3	0.13
International normalised ratio abnormal	1	(0.0)	1	0.05	0			
International normalised ratio decreased	1	(0.0)	1	0.05	0			
International normalised ratio increased	1	(0.0)	2	0.09	0			
Red blood cell count decreased	1	(0.0)	1	0.05	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Transferrin saturation decreased	1	(0.0)	1	0.05	0			
Blood urine present	1	(0.0)	3	0.13	1	(0.0)	1	0.08
Bone density decreased	1	(0.0)	1	0.04	0			
Electrocardiogram ST segment abnormal	1	(0.0)	1	0.04	0			
Electrocardiogram T wave inversion	1	(0.0)	1	0.04	1	(0.0)	1	0.08
QRS axis abnormal	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Thyroid function test abnormal	1	(0.0)	1	0.04	0			
Transaminases increased	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Platelet count decreased	0				3	(0.1)	3	0.24
Cardiac murmur	0				2	(0.1)	2	0.14
Blood glucose increased	0				2	(0.1)	2	0.14
Haemoglobin decreased	0				2	(0.1)	2	0.14
Antinuclear antibody positive	0				1	(0.0)	1	0.04
Breath sounds abnormal	0				1	(0.0)	1	0.04
Carbohydrate antigen 19-9 increased	0				1	(0.0)	1	0.04
Ejection fraction decreased	0				1	(0.0)	1	0.04
Grip strength decreased	0				1	(0.0)	1	0.04
Lipase increased	0				1	(0.0)	1	0.04
Vitamin D decreased	0				1	(0.0)	1	0.04
Amylase increased	0				1	(0.0)	1	0.08
Glomerular filtration rate decreased	0				1	(0.0)	1	0.08
Haematocrit increased	0				1	(0.0)	1	0.08
Haemoglobin increased	0				1	(0.0)	1	0.08
Blood pressure decreased	0				1	(0.0)	1	0.05
Cardiac stress test abnormal	0				1	(0.0)	1	0.05
Electrocardiogram repolarisation abnormality	0				1	(0.0)	1	0.05
Lipids increased	0				1	(0.0)	1	0.05
Blood glucose decreased	0				1	(0.0)	1	0.08
Electrocardiogram P wave biphasic	0				1	(0.0)	1	0.08
Electrocardiogram ST segment depression	0				1	(0.0)	1	0.08
Free fatty acids increased	0				1	(0.0)	1	0.08
Intraocular pressure increased	0				1	(0.0)	1	0.08
Blood uric acid increased	0				1	(0.0)	1	0.09
Lipids abnormal	0				1	(0.0)	1	0.09
White blood cell count decreased	0				1	(0.0)	1	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vascular disorders	79	(3.6)	88	5.30	80	(3.7)	99	6.07
Hypertension	37	(1.7)	37	2.37	38	(1.8)	43	2.71
Hypotension	6	(0.3)	6	0.34	3	(0.1)	3	0.17
Peripheral arterial occlusive disease	4	(0.2)	5	0.30	2	(0.1)	2	0.09
Arteriosclerosis	4	(0.2)	4	0.23	7	(0.3)	7	0.42
Peripheral coldness	3	(0.1)	3	0.14	1	(0.0)	1	0.05
Superficial vein thrombosis	3	(0.1)	3	0.14	0			
Orthostatic hypotension	2	(0.1)	2	0.16	0			
Haematoma	2	(0.1)	2	0.13	3	(0.1)	3	0.21
Peripheral artery stenosis	2	(0.1)	5	0.33	0			
Peripheral venous disease	2	(0.1)	2	0.13	3	(0.1)	3	0.17
Aortic arteriosclerosis	2	(0.1)	2	0.09	4	(0.2)	4	0.29
Blood pressure inadequately controlled	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Arterial insufficiency	1	(0.0)	1	0.08	0			
Varicose ulceration	1	(0.0)	1	0.08	0			
Deep vein thrombosis	1	(0.0)	1	0.08	0			
Diabetic vascular disorder	1	(0.0)	1	0.08	2	(0.1)	2	0.16
Hypertensive crisis	1	(0.0)	1	0.08	2	(0.1)	4	0.29
Aortic stenosis	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Brachiocephalic arteriosclerosis	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Flushing	1	(0.0)	1	0.05	0			
Hypertensive urgency	1	(0.0)	1	0.05	2	(0.1)	3	0.17
Peripheral artery occlusion	1	(0.0)	1	0.05	0			
Peripheral vascular disorder	1	(0.0)	1	0.05	0			
Thrombosis	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Varicose vein	1	(0.0)	1	0.05	3	(0.1)	3	0.18
Hot flush	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Venous stenosis	1	(0.0)	1	0.04	0			
Intermittent claudication	0				2	(0.1)	2	0.09
Aneurysm	0				1	(0.0)	1	0.04
Aortic aneurysm	0				1	(0.0)	1	0.04
Peripheral ischaemia	0				1	(0.0)	1	0.04
Phlebitis	0				1	(0.0)	1	0.04
Blood pressure fluctuation	0				1	(0.0)	1	0.08
Neovascularisation	0				1	(0.0)	1	0.08
Thrombophlebitis	0				1	(0.0)	1	0.08
Iliac artery stenosis	0				1	(0.0)	1	0.05
Macroangiopathy	0				1	(0.0)	1	0.05
Aortic dilatation	0				1	(0.0)	1	0.08
Peripheral artery aneurysm	0				1	(0.0)	1	0.08

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Adverse events by system organ class and preferred term - on-treatment/main-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	54	(2.5)	65	4.04	54	(2.5)	70	4.05
Renal cyst	7	(0.3)	7	0.45	5	(0.2)	5	0.31
Pollakiuria	5	(0.2)	5	0.36	2	(0.1)	2	0.09
Nephrolithiasis	5	(0.2)	5	0.23	4	(0.2)	6	0.37
Renal impairment	4	(0.2)	4	0.25	3	(0.1)	3	0.14
Chronic kidney disease	4	(0.2)	4	0.29	6	(0.3)	6	0.36
Dysuria	4	(0.2)	5	0.26	4	(0.2)	4	0.22
Renal pain	3	(0.1)	3	0.23	0			
Diabetic nephropathy	3	(0.1)	3	0.17	4	(0.2)	4	0.34
Acute kidney injury	3	(0.1)	3	0.20	5	(0.2)	5	0.22
Ureterolithiasis	3	(0.1)	3	0.17	3	(0.1)	3	0.14
Microalbuminuria	2	(0.1)	2	0.14	1	(0.0)	1	0.04
Urine odour abnormal	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Nocturia	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Bladder prolapse	1	(0.0)	1	0.08	0			
Hydronephrosis	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Nephrotic syndrome	1	(0.0)	1	0.08	0			
Polyuria	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Urethral stenosis	1	(0.0)	1	0.08	0			
Chromaturia	1	(0.0)	1	0.08	0			
Renal failure	1	(0.0)	1	0.08	0			
Haematuria	1	(0.0)	2	0.16	5	(0.2)	5	0.26
Calculus urinary	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Pyelocaliectasis	1	(0.0)	1	0.05	0			
Renal colic	1	(0.0)	1	0.05	3	(0.1)	3	0.20
Hypertonic bladder	1	(0.0)	1	0.04	0			
Proteinuria	1	(0.0)	1	0.04	0			
Urinary incontinence	1	(0.0)	1	0.04	3	(0.1)	3	0.14
Urinary retention	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Urinary tract disorder	1	(0.0)	1	0.04	0			
Hydrocalyx	0				2	(0.1)	2	0.17
Bladder mass	0				1	(0.0)	1	0.04
Cystitis haemorrhagic	0				1	(0.0)	1	0.04
Renal mass	0				1	(0.0)	1	0.04
Stress urinary incontinence	0				1	(0.0)	1	0.04
Urinary tract inflammation	0				1	(0.0)	1	0.04
Nephropathy	0				1	(0.0)	1	0.08
Urinary tract obstruction	0				1	(0.0)	1	0.05
Micturition urgency	0				1	(0.0)	1	0.08
Strangury	0				1	(0.0)	1	0.08
Hypertensive nephropathy	0				1	(0.0)	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. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Psychiatric disorders	41	(1.9)	45	2.70	43	(2.0)	46	3.08
Insomnia	11	(0.5)	11	0.69	6	(0.3)	7	0.42
Depression	8	(0.4)	8	0.43	12	(0.6)	12	0.82
Anxiety	6	(0.3)	6	0.36	10	(0.5)	10	0.64
Sleep disorder	5	(0.2)	5	0.28	4	(0.2)	4	0.32
Depressed mood	2	(0.1)	2	0.14	0			
Irritability	2	(0.1)	2	0.12	0			
Attention deficit hyperactivity disorder	1	(0.0)	1	0.09	0			
Adjustment disorder	1	(0.0)	1	0.08	0			
Agitation	1	(0.0)	1	0.08	0			
Drug abuse	1	(0.0)	1	0.08	0			
Mental status changes	1	(0.0)	1	0.08	0			
Nightmare	1	(0.0)	1	0.05	0			
Adjustment disorder with mixed anxiety and depressed mood	1	(0.0)	1	0.04	0			
Disorientation	1	(0.0)	1	0.04	0			
Listless	1	(0.0)	1	0.04	0			
Post-traumatic stress disorder	1	(0.0)	1	0.04	0			
Stress	1	(0.0)	1	0.04	0			
Fear	0				2	(0.1)	2	0.16
Anxiety disorder	0				1	(0.0)	1	0.04
Drug dependence	0				1	(0.0)	1	0.04
Affect lability	0				1	(0.0)	1	0.08
Mixed anxiety and depressive disorder	0				1	(0.0)	1	0.08
Phobia	0				1	(0.0)	1	0.08
Bruxism	0				1	(0.0)	1	0.05
Mood swings	0				1	(0.0)	1	0.05
Persistent depressive disorder	0				1	(0.0)	1	0.05
Adjustment disorder with depressed mood	0				1	(0.0)	1	0.08
Emotional distress	0				1	(0.0)	1	0.08
Major depression	0				1	(0.0)	1	0.08
Blood and lymphatic system disorders	36	(1.7)	38	2.42	33	(1.5)	33	1.99
Anaemia	20	(0.9)	22	1.42	14	(0.6)	14	0.81
Lymphadenopathy	3	(0.1)	3	0.19	2	(0.1)	2	0.14
Eosinophilia	3	(0.1)	3	0.17	2	(0.1)	2	0.13
Iron deficiency anaemia	2	(0.1)	2	0.13	4	(0.2)	4	0.26
Lymphadenitis	1	(0.0)	1	0.09	0			
Leukopenia	1	(0.0)	1	0.08	0			
Blood loss anaemia	1	(0.0)	1	0.08	2	(0.1)	2	0.09
Lymphadenopathy mediastinal	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Polycythaemia	1	(0.0)	1	0.05	0			
Thrombocytopenia	1	(0.0)	1	0.05	1	(0.0)	1	0.09
Leukocytosis	1	(0.0)	1	0.04	3	(0.1)	3	0.13
Splenomegaly	1	(0.0)	1	0.04	0			
Pancytopenia	0				1	(0.0)	1	0.04
Hypochromic anaemia	0				1	(0.0)	1	0.05
Normocytic anaemia	0				1	(0.0)	1	0.08
Thrombocytosis	0				1	(0.0)	1	0.08
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	35	(1.6)	43	2.59	29	(1.3)	43	2.50
Colon adenoma	3	(0.1)	3	0.20	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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Eye naevus	3	(0.1)	4	0.26	0			
Haemangioma of liver	2	(0.1)	2	0.14	0			
Pancreatic neoplasm	2	(0.1)	2	0.13	0			
Seborrhoeic keratosis	2	(0.1)	3	0.14	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Colorectal cancer	2	(0.1)	2	0.12	0			
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Benign neoplasm of thyroid gland	1	(0.0)	1	0.09	0			
Melanocytic naevus	1	(0.0)	1	0.09	0			
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Gastric cancer	1	(0.0)	1	0.08	0			
Bladder papilloma	1	(0.0)	1	0.08	0			
Lung cancer metastatic	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Skin papilloma	1	(0.0)	1	0.08	0			
Osteoma	1	(0.0)	1	0.08	0			
Small cell lung cancer	1	(0.0)	1	0.08	0			
Acrochordon	1	(0.0)	1	0.05	0			
Basal cell carcinoma	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Neoplasm skin	1	(0.0)	1	0.05	0			
Oral fibroma	1	(0.0)	1	0.05	0			
Prostate cancer	1	(0.0)	1	0.05	0			
Salivary gland neoplasm	1	(0.0)	1	0.05	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Invasive ductal breast carcinoma	1	(0.0)	1	0.04	0			
Invasive lobular breast carcinoma	1	(0.0)	1	0.04	0			
Lipoma	1	(0.0)	1	0.04	0			
Pancreatic carcinoma	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Renal neoplasm	1	(0.0)	1	0.04	0			
Squamous cell carcinoma of skin	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Uterine leiomyoma	0				5	(0.2)	5	0.36
Benign renal neoplasm	0				2	(0.1)	2	0.14
Adrenal adenoma	0				2	(0.1)	2	0.16
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Bowen's disease	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Gastrointestinal tract adenoma	0				1	(0.0)	1	0.04
Invasive breast carcinoma	0				1	(0.0)	1	0.04
Malignant melanoma	0				1	(0.0)	1	0.04
Malignant peritoneal neoplasm	0				1	(0.0)	1	0.04
Metastases to bone marrow	0				1	(0.0)	1	0.04
Metastases to lymph nodes	0				1	(0.0)	1	0.04
Myxoma	0				1	(0.0)	1	0.04
Prostatic adenoma	0				1	(0.0)	1	0.04
Renal hamartoma	0				1	(0.0)	1	0.04
Small intestine neuroendocrine tumour	0				1	(0.0)	1	0.08
Uterine cancer	0				1	(0.0)	1	0.08
Colon cancer	0				1	(0.0)	1	0.05
Dysplastic naevus	0				1	(0.0)	1	0.05
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Malignant melanoma in situ	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05

%: 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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Breast cancer	0				1	(0.0)	1	0.08
Colon cancer stage II	0				1	(0.0)	1	0.08
Lymphangioma	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Reproductive system and breast disorders	33	(1.5)	33	2.03	27	(1.2)	33	1.99
Benign prostatic hyperplasia	6	(0.3)	6	0.39	3	(0.1)	3	0.17
Erectile dysfunction	5	(0.2)	5	0.26	1	(0.0)	1	0.08
Intermenstrual bleeding	2	(0.1)	2	0.16	0			
Uterine polyp	2	(0.1)	2	0.09	0			
Dysmenorrhoea	1	(0.0)	1	0.09	2	(0.1)	2	0.14
Premenstrual syndrome	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Prostatomegaly	1	(0.0)	1	0.09	0			
Cervical polyp	1	(0.0)	1	0.08	0			
Prostatitis	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Breast pain	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Menstruation delayed	1	(0.0)	1	0.08	0			
Prostatic calcification	1	(0.0)	1	0.08	0			
Breast mass	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Menopausal symptoms	1	(0.0)	1	0.05	0			
Ovarian cyst	1	(0.0)	1	0.05	0			
Pruritus genital	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Uterine prolapse	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Vulvovaginal pruritus	1	(0.0)	1	0.05	2	(0.1)	2	0.09
Atrophic vulvovaginitis	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Ejaculation failure	1	(0.0)	1	0.04	0			
Menstruation irregular	1	(0.0)	1	0.04	0			
Pelvic discomfort	1	(0.0)	1	0.04	0			
Vaginal haemorrhage	0				2	(0.1)	2	0.09
Vaginal discharge	0				2	(0.1)	2	0.12
Colpocele	0				1	(0.0)	1	0.04
Genital prolapse	0				1	(0.0)	1	0.04
Testicular cyst	0				1	(0.0)	1	0.04
Uterine enlargement	0				1	(0.0)	1	0.04
Menopausal disorder	0				1	(0.0)	1	0.08
Galactorrhoea	0				1	(0.0)	1	0.05
Penile rash	0				1	(0.0)	2	0.09
Vulvovaginal dryness	0				1	(0.0)	1	0.05
Ectropion of cervix	0				1	(0.0)	1	0.09
Fibrocystic breast disease	0				1	(0.0)	1	0.09
Ovarian disorder	0				1	(0.0)	1	0.09
Penile pain	0				1	(0.0)	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. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events by system organ class and preferred term - on-treatment/main-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 and labyrinth disorders	28	(1.3)	31	1.77	24	(1.1)	25	1.58
Vertigo	10	(0.5)	11	0.63	9	(0.4)	10	0.61
Ear pain	6	(0.3)	6	0.39	2	(0.1)	2	0.17
Hypoacusis	2	(0.1)	2	0.12	3	(0.1)	3	0.14
Tinnitus	2	(0.1)	2	0.09	2	(0.1)	2	0.13
Deafness bilateral	2	(0.1)	2	0.09	0			
Vertigo positional	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Deafness neurosensory	1	(0.0)	1	0.09	0			
Cerumen impaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Ear inflammation	1	(0.0)	1	0.05	0			
Eustachian tube dysfunction	1	(0.0)	1	0.05	1	(0.0)	1	0.08
External ear pain	1	(0.0)	1	0.04	0			
Meniere's disease	1	(0.0)	1	0.04	0			
Motion sickness	0				1	(0.0)	1	0.04
Ear discomfort	0				1	(0.0)	1	0.08
Middle ear inflammation	0				1	(0.0)	1	0.08
Presbyacusis	0				1	(0.0)	1	0.05
Deafness unilateral	0				1	(0.0)	1	0.08
Hepatobiliary disorders	24	(1.1)	31	1.98	25	(1.2)	29	1.85
Hepatic steatosis	11	(0.5)	11	0.69	10	(0.5)	10	0.60
Cholelithiasis	3	(0.1)	3	0.14	1	(0.0)	1	0.04
Gallbladder polyp	2	(0.1)	2	0.17	3	(0.1)	3	0.27
Hypertransaminasaemia	2	(0.1)	3	0.19	0			
Hepatomegaly	2	(0.1)	2	0.12	0			
Hepatic calcification	1	(0.0)	1	0.09	0			
Alcoholic liver disease	1	(0.0)	1	0.08	0			
Cholecystitis	1	(0.0)	1	0.08	0			
Hepatic function abnormal	1	(0.0)	1	0.08	2	(0.1)	2	0.13
Cholecystitis chronic	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Hyperplastic cholecystopathy	1	(0.0)	1	0.08	0			
Gallbladder cholesterolosis	1	(0.0)	1	0.05	0			
Liver disorder	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Non-alcoholic steatohepatitis	1	(0.0)	1	0.05	0			
Hepatic mass	1	(0.0)	1	0.04	0			
Nonalcoholic fatty liver disease	0				2	(0.1)	2	0.09
Hepatic cirrhosis	0				2	(0.1)	2	0.13
Bile duct stone	0				1	(0.0)	2	0.09
Biliary dyskinesia	0				1	(0.0)	1	0.08
Hepatic cyst	0				1	(0.0)	1	0.05
Steatohepatitis	0				1	(0.0)	1	0.05
Biliary colic	0				1	(0.0)	1	0.08
Gallbladder disorder	0				1	(0.0)	1	0.09
Immune system disorders	14	(0.6)	15	0.95	16	(0.7)	17	1.13
Seasonal allergy	8	(0.4)	8	0.43	9	(0.4)	9	0.60
Hypersensitivity	3	(0.1)	3	0.27	1	(0.0)	1	0.08
Anaphylactic reaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Drug hypersensitivity	1	(0.0)	1	0.08	0			
Allergy to arthropod bite	1	(0.0)	1	0.05	2	(0.1)	2	0.16
Food allergy	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Immunisation reaction	0				1	(0.0)	2	0.09
Allergy to arthropod sting	0				1	(0.0)	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 system organ class and preferred term - on-treatment/main-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	6	(0.3)	6	0.41	5	(0.2)	5	0.26
Type V hyperlipidaemia	3	(0.1)	3	0.20	1	(0.0)	1	0.08
Cystic fibrosis lung	1	(0.0)	1	0.08	0			
Corneal dystrophy	1	(0.0)	1	0.08	0			
Hydrocele	1	(0.0)	1	0.05	0			
Atrial septal defect	0				1	(0.0)	1	0.04
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Myotonic dystrophy	0				1	(0.0)	1	0.04
Congenital syphilitic osteochondritis	0				1	(0.0)	1	0.05
Surgical and medical procedures	6	(0.3)	6	0.44	6	(0.3)	6	0.34
Cardiac ablation	1	(0.0)	1	0.09	0			
Skin neoplasm excision	1	(0.0)	1	0.09	1	(0.0)	1	0.04
Shoulder operation	1	(0.0)	1	0.08	0			
Tooth extraction	1	(0.0)	1	0.08	0			
Knee operation	1	(0.0)	1	0.05	0			
Cardiac pacemaker replacement	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Spinal operation	0				1	(0.0)	1	0.04
Large intestinal polypectomy	0				1	(0.0)	1	0.05
Removal of foreign body	0				1	(0.0)	1	0.05
Toe amputation	0				1	(0.0)	1	0.08
Endocrine disorders	6	(0.3)	6	0.34	19	(0.9)	19	1.12
Thyroid mass	2	(0.1)	2	0.09	2	(0.1)	2	0.12
Hypothyroidism	2	(0.1)	2	0.12	5	(0.2)	5	0.31
Hypogonadism	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Autoimmune thyroiditis	1	(0.0)	1	0.04	0			
Hyperthyroidism	0				2	(0.1)	2	0.09
Goitre	0				2	(0.1)	2	0.09
Adrenocortical insufficiency acute	0				2	(0.1)	2	0.16
Adrenal mass	0				1	(0.0)	1	0.04
Hyperplasia adrenal	0				1	(0.0)	1	0.05
Hyperprolactinaemia	0				1	(0.0)	1	0.05
Secondary hypogonadism	0				1	(0.0)	1	0.08
Inappropriate antidiuretic hormone secretion	0				1	(0.0)	1	0.08
Social circumstances	0				1	(0.0)	1	0.08
Menopause	0				1	(0.0)	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.

7.2.12 Adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	1139	(60.6)	3478	238.93	1073	(57.1)	3259	223.24
Infections and infestations	544	(28.9)	773	53.73	523	(27.8)	757	51.03
COVID-19	152	(8.1)	155	10.50	160	(8.5)	165	10.51
Nasopharyngitis	83	(4.4)	99	7.07	79	(4.2)	92	6.52
Upper respiratory tract infection	62	(3.3)	75	4.96	45	(2.4)	48	3.23
Urinary tract infection	37	(2.0)	40	2.87	44	(2.3)	48	3.08
Influenza	28	(1.5)	31	2.60	28	(1.5)	31	2.57
Gastroenteritis	26	(1.4)	26	2.07	16	(0.9)	17	1.33
Bronchitis	26	(1.4)	27	1.93	17	(0.9)	17	1.17
Pharyngitis	16	(0.9)	18	1.12	17	(0.9)	20	1.38
Pneumonia	14	(0.7)	14	1.01	6	(0.3)	6	0.43
Sinusitis	14	(0.7)	16	1.08	17	(0.9)	20	1.33
COVID-19 pneumonia	14	(0.7)	14	0.97	10	(0.5)	10	0.64
Cystitis	12	(0.6)	13	0.92	16	(0.9)	18	1.23
Herpes zoster	10	(0.5)	10	0.61	15	(0.8)	16	1.00
Respiratory tract infection viral	9	(0.5)	10	0.81	8	(0.4)	9	0.76
Conjunctivitis	8	(0.4)	8	0.50	7	(0.4)	7	0.49
Respiratory tract infection	8	(0.4)	8	0.54	6	(0.3)	6	0.40
Tooth infection	8	(0.4)	10	0.67	8	(0.4)	8	0.65
Otitis media	7	(0.4)	7	0.56	4	(0.2)	4	0.29
Tooth abscess	7	(0.4)	7	0.53	7	(0.4)	8	0.54
Rhinitis	7	(0.4)	7	0.41	7	(0.4)	9	0.67
Fungal infection	7	(0.4)	8	0.57	2	(0.1)	2	0.15
Viral infection	6	(0.3)	6	0.40	9	(0.5)	12	0.67
Gastroenteritis viral	5	(0.3)	5	0.31	4	(0.2)	4	0.25
Lower respiratory tract infection	5	(0.3)	5	0.27	2	(0.1)	4	0.22
Vaginal infection	5	(0.3)	5	0.38	3	(0.2)	3	0.20
Acute sinusitis	5	(0.3)	5	0.30	3	(0.2)	3	0.19
Periodontitis	4	(0.2)	4	0.29	6	(0.3)	6	0.44
Ear infection	4	(0.2)	4	0.25	5	(0.3)	5	0.34
Cellulitis	4	(0.2)	4	0.25	8	(0.4)	9	0.67
Coronavirus infection	4	(0.2)	4	0.21	4	(0.2)	6	0.40
Vulvovaginal candidiasis	3	(0.2)	4	0.25	4	(0.2)	4	0.22
Localised infection	3	(0.2)	3	0.20	2	(0.1)	2	0.14
Wound infection	3	(0.2)	3	0.23	1	(0.1)	1	0.09
Tonsillitis	3	(0.2)	3	0.20	2	(0.1)	2	0.15
Erysipelas	3	(0.2)	3	0.20	2	(0.1)	3	0.23
Laryngitis	3	(0.2)	3	0.16	4	(0.2)	4	0.29
Respiratory syncytial virus infection	3	(0.2)	3	0.20	0			
Genital infection	3	(0.2)	3	0.19	1	(0.1)	1	0.09
Gastrointestinal infection	2	(0.1)	2	0.18	3	(0.2)	4	0.21
Onychomycosis	2	(0.1)	2	0.14	4	(0.2)	4	0.21
Furuncle	2	(0.1)	3	0.20	2	(0.1)	2	0.11
Oral herpes	2	(0.1)	3	0.28	2	(0.1)	2	0.11
Sepsis	2	(0.1)	2	0.18	1	(0.1)	1	0.05
Skin infection	2	(0.1)	2	0.15	1	(0.1)	1	0.09
Tinea infection	2	(0.1)	2	0.15	0			
Abscess	2	(0.1)	2	0.15	1	(0.1)	1	0.05

%: 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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Osteomyelitis	2	(0.1)	2	0.15	0			
Vulvovaginal mycotic infection	2	(0.1)	2	0.15	0			
Candida infection	2	(0.1)	2	0.11	1	(0.1)	1	0.09
Gingivitis	2	(0.1)	3	0.16	4	(0.2)	4	0.33
Hordeolum	2	(0.1)	2	0.11	3	(0.2)	3	0.23
Fungal skin infection	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Helicobacter infection	2	(0.1)	2	0.14	2	(0.1)	2	0.15
Subcutaneous abscess	2	(0.1)	2	0.14	2	(0.1)	3	0.16
Otitis externa	2	(0.1)	2	0.14	3	(0.2)	3	0.16
Paronychia	2	(0.1)	2	0.14	2	(0.1)	3	0.28
Acarodermatitis	2	(0.1)	2	0.10	4	(0.2)	4	0.21
Abscess limb	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Anal abscess	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Enteritis infectious	1	(0.1)	1	0.09	0			
Kidney infection	1	(0.1)	1	0.09	0			
Paraspinal abscess	1	(0.1)	1	0.09	0			
Pulpitis dental	1	(0.1)	1	0.09	4	(0.2)	4	0.33
Pustule	1	(0.1)	1	0.09	0			
Tinea versicolour	1	(0.1)	1	0.09	0			
Varicella zoster virus infection	1	(0.1)	1	0.09	0			
Vulvitis	1	(0.1)	1	0.09	0			
Escherichia bacteraemia	1	(0.1)	1	0.09	0			
Genital candidiasis	1	(0.1)	1	0.09	0			
Injection site abscess	1	(0.1)	1	0.09	0			
Oral candidiasis	1	(0.1)	1	0.09	0			
Postoperative wound infection	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Suspected COVID-19	1	(0.1)	1	0.09	0			
Tinea pedis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Bacteraemia	1	(0.1)	1	0.09	0			
Cholecystitis infective	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Diabetic foot infection	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Infected dermal cyst	1	(0.1)	1	0.09	0			
Pharyngotonsillitis	1	(0.1)	1	0.09	2	(0.1)	3	0.16
Pneumonia viral	1	(0.1)	1	0.09	0			
Pulmonary tuberculoma	1	(0.1)	1	0.09	0			
Viral tracheitis	1	(0.1)	1	0.09	0			
Asymptomatic COVID-19	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Bacterial infection	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Balanitis candida	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Chlamydial infection	1	(0.1)	1	0.05	0			
Chronic tonsillitis	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Dermatophytosis of nail	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Escherichia urinary tract infection	1	(0.1)	1	0.05	0			
Folliculitis	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Genital infection fungal	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Helicobacter gastritis	1	(0.1)	1	0.05	0			
Herpes simplex	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Herpes virus infection	1	(0.1)	1	0.05	0			
Infected bite	1	(0.1)	1	0.05	0			
Laryngopharyngitis	1	(0.1)	1	0.05	1	(0.1)	2	0.10
Mastitis	1	(0.1)	1	0.05	0			
Oropharyngeal candidiasis	1	(0.1)	1	0.05	0			
Otitis media chronic	1	(0.1)	1	0.05	0			
Pericoronitis	1	(0.1)	1	0.05	0			

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Adverse events by system organ class and preferred term - on-treatment/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	1	(0.1)	1	0.05	0			
Tracheitis	1	(0.1)	1	0.05	0			
Urethritis	1	(0.1)	1	0.05	0			
Viral upper respiratory tract infection	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Appendicitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Chronic sinusitis	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Clostridium difficile colitis	1	(0.1)	1	0.05	0			
Clostridium difficile infection	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Ear infection fungal	1	(0.1)	1	0.05	0			
Gangrene	1	(0.1)	1	0.05	0			
Nail infection	1	(0.1)	2	0.10	1	(0.1)	1	0.05
Peritonsillar abscess	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Post-acute COVID-19 syndrome	1	(0.1)	2	0.10	0			
Pyelonephritis	1	(0.1)	1	0.05	0			
Skin candida	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Tinea cruris	1	(0.1)	1	0.05	0			
Viral pharyngitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Diverticulitis	0				5	(0.3)	5	0.27
Otitis media acute	0				3	(0.2)	3	0.20
Breast abscess	0				3	(0.2)	3	0.20
Eye infection	0				3	(0.2)	3	0.28
Urosepsis	0				2	(0.1)	2	0.14
Post procedural infection	0				2	(0.1)	2	0.15
Soft tissue infection	0				2	(0.1)	2	0.18
Abdominal abscess	0				1	(0.1)	1	0.05
Herpes zoster infection neurological	0				1	(0.1)	1	0.05
Sinusitis bacterial	0				1	(0.1)	1	0.05
Sweat gland infection	0				1	(0.1)	1	0.05
Viral rhinitis	0				1	(0.1)	1	0.09
Body tinea	0				1	(0.1)	1	0.05
Breast cellulitis	0				1	(0.1)	1	0.05
Chronic hepatitis C	0				1	(0.1)	1	0.05
Empyema	0				1	(0.1)	1	0.05
Endophthalmitis	0				1	(0.1)	1	0.05
Epididymitis	0				1	(0.1)	1	0.05
Eye infection bacterial	0				1	(0.1)	1	0.05
Fungal balanitis	0				1	(0.1)	1	0.05
Gastroenteritis norovirus	0				1	(0.1)	1	0.05
Giardiasis	0				1	(0.1)	1	0.05
Herpes dermatitis	0				1	(0.1)	1	0.05
Labyrinthitis	0				1	(0.1)	1	0.05
Lyme disease	0				1	(0.1)	1	0.05
Oophoritis	0				1	(0.1)	1	0.05
Parotitis	0				1	(0.1)	1	0.05
Peri-implantitis	0				1	(0.1)	1	0.05
Rotavirus infection	0				1	(0.1)	1	0.05
Salpingitis	0				1	(0.1)	1	0.05
Skin bacterial infection	0				1	(0.1)	1	0.05
Varicella	0				1	(0.1)	1	0.05
Bartholinitis	0				1	(0.1)	1	0.09
Infective iritis	0				1	(0.1)	1	0.09
Campylobacter gastroenteritis	0				1	(0.1)	1	0.09
Gastrointestinal disorders	251	(13.4)	380	25.72	221	(11.8)	302	21.04

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Diarrhoea	84	(4.5)	102	7.03	51	(2.7)	52	3.74
Nausea	37	(2.0)	38	2.55	27	(1.4)	29	1.99
Vomiting	24	(1.3)	32	2.46	16	(0.9)	19	1.25
Constipation	16	(0.9)	19	1.38	16	(0.9)	16	1.20
Abdominal pain	16	(0.9)	16	1.07	18	(1.0)	19	1.36
Toothache	13	(0.7)	13	0.77	10	(0.5)	13	1.12
Gastrooesophageal reflux disease	13	(0.7)	13	0.84	14	(0.7)	14	0.98
Abdominal pain upper	13	(0.7)	15	1.01	15	(0.8)	16	1.04
Dental caries	11	(0.6)	13	0.69	10	(0.5)	10	0.76
Chronic gastritis	8	(0.4)	8	0.58	4	(0.2)	4	0.25
Dyspepsia	7	(0.4)	7	0.52	8	(0.4)	8	0.54
Abdominal distension	7	(0.4)	7	0.41	4	(0.2)	4	0.29
Haemorrhoids	7	(0.4)	7	0.45	3	(0.2)	3	0.24
Gastritis	7	(0.4)	7	0.52	9	(0.5)	9	0.62
Food poisoning	5	(0.3)	5	0.34	4	(0.2)	5	0.42
Flatulence	4	(0.2)	4	0.29	2	(0.1)	2	0.18
Abdominal pain lower	4	(0.2)	4	0.29	2	(0.1)	2	0.11
Large intestine polyp	4	(0.2)	4	0.25	6	(0.3)	7	0.41
Abdominal discomfort	3	(0.2)	3	0.20	5	(0.3)	6	0.44
Enterocolitis	3	(0.2)	4	0.22	0			
Hypoaesthesia oral	3	(0.2)	5	0.42	0			
Diverticulum intestinal	3	(0.2)	3	0.16	1	(0.1)	1	0.05
Hyperaesthesia teeth	2	(0.1)	2	0.14	0			
Gastric polyps	2	(0.1)	2	0.15	2	(0.1)	2	0.15
Hiatus hernia	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Dry mouth	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Rectal polyp	2	(0.1)	2	0.11	2	(0.1)	2	0.11
Aphthous ulcer	2	(0.1)	2	0.10	0			
Inguinal hernia	2	(0.1)	2	0.10	1	(0.1)	2	0.11
Diverticulum	1	(0.1)	1	0.09	3	(0.2)	3	0.20
Gastrointestinal angiodysplasia	1	(0.1)	1	0.09	0			
Gingival bleeding	1	(0.1)	1	0.09	0			
Intra-abdominal haematoma	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Tongue rough	1	(0.1)	1	0.09	0			
Gastric dilatation	1	(0.1)	1	0.09	0			
Noninfective gingivitis	1	(0.1)	1	0.09	0			
Oral pain	1	(0.1)	1	0.09	0			
Vomiting projectile	1	(0.1)	1	0.09	0			
Pancreatic duct dilatation	1	(0.1)	1	0.09	0			
Pancreatic failure	1	(0.1)	1	0.09	0			
Pancreatitis chronic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Proctalgia	1	(0.1)	1	0.09	0			
Anal pruritus	1	(0.1)	1	0.05	0			
Colitis	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Colitis ischaemic	1	(0.1)	1	0.05	0			
Frequent bowel movements	1	(0.1)	1	0.05	0			
Haematochezia	1	(0.1)	1	0.05	0			
Loose tooth	1	(0.1)	1	0.05	0			
Oral discomfort	1	(0.1)	1	0.05	0			
Pancreatitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Periodontal disease	1	(0.1)	1	0.05	2	(0.1)	2	0.18
Tooth disorder	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Tooth impacted	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Abdominal wall disorder	1	(0.1)	1	0.05	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Anal fissure	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Colitis microscopic	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Diabetic gastropathy	1	(0.1)	1	0.05	0			
Eosinophilic oesophagitis	1	(0.1)	1	0.05	0			
Eructation	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Gastric ulcer	1	(0.1)	1	0.05	0			
Gastrointestinal haemorrhage	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Haemorrhoidal haemorrhage	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Impaired gastric emptying	1	(0.1)	1	0.05	0			
Intestinal dilatation	1	(0.1)	1	0.05	0			
Lip swelling	1	(0.1)	1	0.05	0			
Umbilical hernia	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Ileus	0				2	(0.1)	2	0.11
Acid peptic disease	0				2	(0.1)	2	0.11
Stomatitis	0				2	(0.1)	2	0.11
Mesenteric panniculitis	0				1	(0.1)	1	0.05
Oesophageal pain	0				1	(0.1)	1	0.05
Peptic ulcer	0				1	(0.1)	1	0.05
Small intestinal obstruction	0				1	(0.1)	1	0.05
Faeces pale	0				1	(0.1)	1	0.09
Gastrointestinal disorder	0				1	(0.1)	1	0.09
Gingival disorder	0				1	(0.1)	1	0.09
Upper gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Crohn's disease	0				1	(0.1)	1	0.05
Duodenitis	0				1	(0.1)	1	0.05
Enteritis	0				1	(0.1)	1	0.05
Epigastric discomfort	0				1	(0.1)	1	0.05
Gastric disorder	0				1	(0.1)	1	0.05
Gastrointestinal inflammation	0				1	(0.1)	1	0.05
Hyperchlorhydria	0				1	(0.1)	1	0.05
Irritable bowel syndrome	0				1	(0.1)	1	0.05
Melaena	0				1	(0.1)	1	0.05
Pancreatitis acute	0				1	(0.1)	1	0.05
Periodontal inflammation	0				1	(0.1)	2	0.11
Rectal prolapse	0				1	(0.1)	1	0.05
Ulcerative gastritis	0				1	(0.1)	1	0.05
Gastrointestinal sounds abnormal	0				1	(0.1)	1	0.09
Odynophagia	0				1	(0.1)	1	0.09
Oesophagitis	0				1	(0.1)	1	0.09
Gastric dysplasia	0				1	(0.1)	1	0.09
Gastric mucosal hypertrophy	0				1	(0.1)	1	0.09
Pancreatic pseudocyst	0				1	(0.1)	1	0.09
Musculoskeletal and connective tissue disorders	246	(13.1)	369	24.91	245	(13.0)	338	23.17
Back pain	62	(3.3)	66	4.50	61	(3.2)	64	4.61
Arthralgia	45	(2.4)	53	3.59	48	(2.6)	54	3.83
Pain in extremity	31	(1.6)	33	2.01	31	(1.6)	37	2.70
Muscle spasms	23	(1.2)	25	1.85	9	(0.5)	9	0.60
Osteoarthritis	21	(1.1)	23	1.50	24	(1.3)	27	1.82
Neck pain	15	(0.8)	15	1.07	8	(0.4)	8	0.51
Myalgia	14	(0.7)	14	1.04	9	(0.5)	9	0.67
Periarthritis	8	(0.4)	8	0.51	6	(0.3)	6	0.36
Intervertebral disc protrusion	8	(0.4)	12	0.71	6	(0.3)	7	0.45

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Tendonitis	8	(0.4)	10	0.67	4	(0.2)	4	0.29
Trigger finger	7	(0.4)	7	0.57	5	(0.3)	7	0.41
Spinal osteoarthritis	6	(0.3)	6	0.40	5	(0.3)	6	0.31
Arthritis	6	(0.3)	6	0.39	6	(0.3)	6	0.48
Rotator cuff syndrome	5	(0.3)	5	0.34	4	(0.2)	4	0.21
Spinal stenosis	4	(0.2)	6	0.47	2	(0.1)	2	0.11
Musculoskeletal stiffness	4	(0.2)	4	0.29	1	(0.1)	1	0.05
Plantar fasciitis	4	(0.2)	5	0.31	3	(0.2)	3	0.16
Bursitis	4	(0.2)	4	0.25	3	(0.2)	3	0.16
Intervertebral disc disorder	3	(0.2)	3	0.20	2	(0.1)	2	0.15
Muscular weakness	3	(0.2)	3	0.23	3	(0.2)	3	0.24
Tendon disorder	3	(0.2)	3	0.23	1	(0.1)	1	0.09
Musculoskeletal chest pain	3	(0.2)	3	0.16	2	(0.1)	2	0.11
Foot deformity	3	(0.2)	5	0.30	3	(0.2)	3	0.24
Exostosis	3	(0.2)	3	0.16	1	(0.1)	1	0.05
Osteoporosis	2	(0.1)	2	0.18	0			
Musculoskeletal pain	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Back disorder	2	(0.1)	2	0.15	0			
Coccydynia	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Fibromyalgia	2	(0.1)	2	0.11	0			
Groin pain	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Synovial cyst	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Joint effusion	2	(0.1)	3	0.23	2	(0.1)	2	0.11
Osteochondrosis	2	(0.1)	2	0.14	4	(0.2)	4	0.29
Chondropathy	2	(0.1)	2	0.11	0			
Polyarthritis	2	(0.1)	2	0.11	0			
Axillary mass	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Flank pain	1	(0.1)	1	0.09	6	(0.3)	7	0.49
Polymyalgia rheumatica	1	(0.1)	1	0.09	1	(0.1)	3	0.27
Soft tissue swelling	1	(0.1)	3	0.27	0			
Arthropathy	1	(0.1)	1	0.09	0			
Muscle contracture	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Pain in jaw	1	(0.1)	1	0.09	0			
Torticollis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Bone cyst	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Costochondritis	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Fistula	1	(0.1)	1	0.05	0			
Lumbar spinal stenosis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Myositis	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Osteopenia	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Spinal pain	1	(0.1)	1	0.05	4	(0.2)	4	0.25
Tenosynovitis	1	(0.1)	1	0.05	9	(0.5)	10	0.61
Acquired claw toe	1	(0.1)	1	0.05	0			
Diastasis recti abdominis	1	(0.1)	1	0.05	0			
Facet joint syndrome	1	(0.1)	1	0.05	0			
Meniscopathy	1	(0.1)	1	0.05	0			
Psoriatic arthropathy	1	(0.1)	1	0.05	0			
Sacroiliitis	1	(0.1)	1	0.05	0			
Joint swelling	0				3	(0.2)	3	0.24
Rheumatoid arthritis	0				2	(0.1)	2	0.14
Dupuytren's contracture	0				2	(0.1)	2	0.11
Haemarthrosis	0				1	(0.1)	1	0.05
Intervertebral disc space narrowing	0				1	(0.1)	2	0.10
Muscle twitching	0				1	(0.1)	1	0.05

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Nodal osteoarthritis	0				1	(0.1)	1	0.05
Scoliosis	0				1	(0.1)	1	0.05
Spinal retrolisthesis	0				1	(0.1)	2	0.10
Bone pain	0				1	(0.1)	1	0.09
Jaw disorder	0				1	(0.1)	1	0.09
Periostitis	0				1	(0.1)	1	0.09
Cervical spinal stenosis	0				1	(0.1)	1	0.05
Limb deformity	0				1	(0.1)	1	0.05
Mastication disorder	0				1	(0.1)	2	0.11
Tenosynovitis stenosans	0				1	(0.1)	1	0.05
Vertebral osteophyte	0				1	(0.1)	1	0.05
Intervertebral disc degeneration	0				1	(0.1)	1	0.09
Neuropathic arthropathy	0				1	(0.1)	1	0.09
Osteochondritis	0				1	(0.1)	1	0.09
General disorders and administration site conditions	199	(10.6)	313	22.68	174	(9.3)	261	17.26
Pyrexia	32	(1.7)	33	2.22	37	(2.0)	39	2.67
Fatigue	27	(1.4)	30	2.02	15	(0.8)	15	0.94
Oedema peripheral	17	(0.9)	17	1.21	9	(0.5)	10	0.61
Injection site reaction	15	(0.8)	29	2.57	6	(0.3)	8	0.53
Chest pain	14	(0.7)	14	0.93	5	(0.3)	5	0.26
Malaise	13	(0.7)	15	0.95	12	(0.6)	16	1.05
Vaccination site pain	10	(0.5)	12	0.91	8	(0.4)	8	0.62
Pain	10	(0.5)	11	0.85	14	(0.7)	15	1.03
Asthenia	10	(0.5)	10	0.72	8	(0.4)	8	0.55
Chest discomfort	8	(0.4)	8	0.58	2	(0.1)	2	0.15
Hunger	6	(0.3)	7	0.41	2	(0.1)	2	0.15
Medical device site bruise	5	(0.3)	7	0.45	1	(0.1)	1	0.05
Peripheral swelling	5	(0.3)	6	0.39	4	(0.2)	4	0.29
Medical device site dermatitis	4	(0.2)	7	0.45	8	(0.4)	14	0.76
Medical device site reaction	4	(0.2)	6	0.44	1	(0.1)	1	0.05
Medical device site pruritus	4	(0.2)	4	0.25	1	(0.1)	1	0.05
Influenza like illness	4	(0.2)	5	0.38	3	(0.2)	3	0.16
Medical device site haemorrhage	4	(0.2)	4	0.22	2	(0.1)	2	0.11
Chills	4	(0.2)	4	0.25	1	(0.1)	1	0.05
Injection site pruritus	4	(0.2)	19	1.66	1	(0.1)	1	0.09
Injection site pain	3	(0.2)	3	0.27	12	(0.6)	30	1.82
Injection site erythema	3	(0.2)	5	0.42	4	(0.2)	4	0.22
Thirst	3	(0.2)	3	0.24	1	(0.1)	1	0.09
Feeling abnormal	3	(0.2)	5	0.35	1	(0.1)	1	0.05
Injection site bruising	3	(0.2)	3	0.23	5	(0.3)	5	0.30
Drug intolerance	3	(0.2)	3	0.16	0			
Gait disturbance	3	(0.2)	3	0.16	1	(0.1)	1	0.05
Medical device site erythema	2	(0.1)	2	0.18	2	(0.1)	2	0.15
Injection site swelling	2	(0.1)	2	0.18	1	(0.1)	1	0.09
Injection site haematoma	2	(0.1)	6	0.55	3	(0.2)	8	0.73
Injection site haemorrhage	2	(0.1)	2	0.18	2	(0.1)	2	0.15
Discomfort	2	(0.1)	2	0.15	1	(0.1)	8	0.74
Injection site hypersensitivity	2	(0.1)	2	0.11	0			
Injection site mass	2	(0.1)	2	0.11	0			
Application site bruise	1	(0.1)	1	0.09	0			
Application site pruritus	1	(0.1)	1	0.09	0			
Inflammation	1	(0.1)	1	0.09	3	(0.2)	3	0.20

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injection site rash	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Oedema	1	(0.1)	1	0.09	3	(0.2)	3	0.20
Oedema due to renal disease	1	(0.1)	1	0.09	0			
Vaccination site inflammation	1	(0.1)	1	0.09	0			
Vaccination site pruritus	1	(0.1)	1	0.09	0			
Xerosis	1	(0.1)	1	0.09	0			
Feeling hot	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Implant site pruritus	1	(0.1)	1	0.05	0			
Injection site dermatitis	1	(0.1)	1	0.05	0			
Medical device site eczema	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Medical device site hypersensitivity	1	(0.1)	1	0.05	0			
Medical device site pain	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Swelling	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Vaccination site reaction	1	(0.1)	1	0.05	0			
Early satiety	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Localised oedema	1	(0.1)	1	0.05	0			
Swelling face	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Vessel puncture site bruise	1	(0.1)	1	0.05	0			
Non-cardiac chest pain	0				4	(0.2)	6	0.31
Death	0				3	(0.2)	3	0.16
Cyst	0				2	(0.1)	2	0.14
Injection site induration	0				2	(0.1)	2	0.14
Hernia	0				1	(0.1)	1	0.05
Systemic inflammatory response syndrome	0				1	(0.1)	1	0.05
Axillary pain	0				1	(0.1)	1	0.09
Facial pain	0				1	(0.1)	1	0.09
Injection site hypertrophy	0				1	(0.1)	1	0.05
Injection site urticaria	0				1	(0.1)	1	0.05
Medical device site haematoma	0				1	(0.1)	1	0.05
Medical device site inflammation	0				1	(0.1)	1	0.05
Procedural failure	0				1	(0.1)	1	0.05
Vaccination site erythema	0				1	(0.1)	1	0.05
Injection site oedema	0				1	(0.1)	1	0.09
Condition aggravated	0				1	(0.1)	1	0.09
Medical device site rash	0				1	(0.1)	1	0.09
Nervous system disorders	180	(9.6)	252	17.62	183	(9.7)	248	17.55
Headache	57	(3.0)	73	5.46	54	(2.9)	67	4.72
Dizziness	38	(2.0)	48	3.35	37	(2.0)	44	3.22
Sciatica	13	(0.7)	13	0.95	12	(0.6)	13	0.85
Carpal tunnel syndrome	11	(0.6)	11	0.74	7	(0.4)	7	0.53
Tremor	11	(0.6)	12	0.71	8	(0.4)	12	1.03
Hypoaesthesia	9	(0.5)	12	0.83	9	(0.5)	10	0.69
Paraesthesia	8	(0.4)	9	0.51	12	(0.6)	12	0.91
Syncope	6	(0.3)	6	0.36	1	(0.1)	1	0.05
Neuropathy peripheral	6	(0.3)	7	0.53	9	(0.5)	9	0.59
Migraine	6	(0.3)	6	0.43	3	(0.2)	3	0.24
Diabetic neuropathy	5	(0.3)	5	0.38	12	(0.6)	12	0.87
Tension headache	3	(0.2)	4	0.25	0			
Transient ischaemic attack	3	(0.2)	3	0.20	3	(0.2)	3	0.20
Dysgeusia	3	(0.2)	3	0.20	0			
Post herpetic neuralgia	2	(0.1)	2	0.14	0			
Cerebrovascular disorder	2	(0.1)	2	0.15	0			

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Adverse events by system organ class and preferred term - on-treatment/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	2	(0.1)	2	0.15	1	(0.1)	1	0.09
Burning sensation	2	(0.1)	2	0.11	3	(0.2)	3	0.20
Neuralgia	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Amnesia	2	(0.1)	2	0.14	0			
Carotid artery stenosis	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Autonomic nervous system imbalance	1	(0.1)	1	0.09	0			
Carotid artery aneurysm	1	(0.1)	1	0.09	0			
Cervicobrachial syndrome	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Facial paralysis	1	(0.1)	1	0.09	0			
Peripheral paralysis	1	(0.1)	1	0.09	0			
Piriformis syndrome	1	(0.1)	1	0.09	0			
Somnolence	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Thalamic infarction	1	(0.1)	1	0.09	0			
Vascular headache	1	(0.1)	1	0.09	0			
Cerebral arteriosclerosis	1	(0.1)	1	0.09	0			
Vascular encephalopathy	1	(0.1)	1	0.09	0			
Ageusia	1	(0.1)	1	0.05	0			
Anosmia	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Balance disorder	1	(0.1)	1	0.05	0			
Cerebral haemorrhage	1	(0.1)	1	0.05	0			
Cervical radiculopathy	1	(0.1)	1	0.05	0			
Dizziness postural	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Lumbar radiculopathy	1	(0.1)	1	0.05	4	(0.2)	5	0.26
Neuroglycopenia	1	(0.1)	1	0.05	1	(0.1)	3	0.16
Presyncope	1	(0.1)	1	0.05	4	(0.2)	4	0.21
Trigeminal neuralgia	1	(0.1)	1	0.05	0			
Cerebral atrophy	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Cluster headache	1	(0.1)	1	0.05	0			
Cognitive disorder	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Disturbance in attention	1	(0.1)	1	0.05	0			
Intracranial pressure increased	1	(0.1)	1	0.05	0			
Cerebrovascular accident	0				2	(0.1)	2	0.14
Lethargy	0				2	(0.1)	2	0.11
Thrombotic stroke	0				2	(0.1)	2	0.15
Cerebral artery embolism	0				1	(0.1)	1	0.05
Dementia Alzheimer's type	0				1	(0.1)	1	0.05
Ischaemic stroke	0				1	(0.1)	1	0.05
Loss of consciousness	0				1	(0.1)	1	0.05
Ophthalmic migraine	0				1	(0.1)	1	0.05
Orthostatic tremor	0				1	(0.1)	1	0.05
Radiculopathy	0				1	(0.1)	1	0.05
White matter lesion	0				1	(0.1)	1	0.05
Basilar migraine	0				1	(0.1)	1	0.09
Essential tremor	0				1	(0.1)	1	0.09
Facial nerve disorder	0				1	(0.1)	1	0.09
Hemiparesis	0				1	(0.1)	1	0.09
Hypoglycaemic coma	0				1	(0.1)	1	0.09
Hyporeflexia	0				1	(0.1)	1	0.09
Morton's neuralgia	0				1	(0.1)	1	0.09
Sleep deficit	0				1	(0.1)	1	0.09
Brain injury	0				1	(0.1)	1	0.05
Carotid arteriosclerosis	0				1	(0.1)	1	0.05
Mental impairment	0				1	(0.1)	1	0.05
Parkinsonian gait	0				1	(0.1)	1	0.05

%: 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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vertebral artery occlusion	0				1	(0.1)	1	0.05
Meralgia paraesthetica	0				1	(0.1)	1	0.09
Myelopathy	0				1	(0.1)	1	0.09
Cerebral infarction	0				1	(0.1)	1	0.09
Restless legs syndrome	0				1	(0.1)	1	0.09
Injury, poisoning and procedural complications	164	(8.7)	204	14.10	147	(7.8)	178	12.85
Fall	19	(1.0)	19	1.22	10	(0.5)	11	0.73
Vaccination complication	15	(0.8)	19	1.35	21	(1.1)	27	1.76
Contusion	14	(0.7)	15	0.99	7	(0.4)	7	0.41
Ligament sprain	9	(0.5)	9	0.66	8	(0.4)	8	0.62
Skin abrasion	8	(0.4)	10	0.68	4	(0.2)	4	0.33
Accidental overdose	7	(0.4)	7	0.56	3	(0.2)	4	0.37
Skin laceration	7	(0.4)	7	0.49	0			
Hand fracture	6	(0.3)	6	0.43	1	(0.1)	1	0.05
Joint injury	5	(0.3)	5	0.38	4	(0.2)	4	0.25
Limb injury	5	(0.3)	5	0.34	6	(0.3)	7	0.56
Overdose	4	(0.2)	4	0.33	3	(0.2)	3	0.24
Rib fracture	4	(0.2)	4	0.29	5	(0.3)	5	0.34
Procedural pain	4	(0.2)	4	0.29	1	(0.1)	1	0.09
Tooth fracture	4	(0.2)	4	0.29	2	(0.1)	2	0.15
Road traffic accident	4	(0.2)	4	0.28	1	(0.1)	1	0.05
Ankle fracture	4	(0.2)	4	0.21	3	(0.2)	3	0.15
Thermal burn	3	(0.2)	3	0.24	2	(0.1)	2	0.15
Arthropod bite	3	(0.2)	3	0.28	3	(0.2)	3	0.24
Incorrect dose administered	3	(0.2)	3	0.28	5	(0.3)	7	0.60
Wound	3	(0.2)	3	0.20	5	(0.3)	5	0.42
Foot fracture	3	(0.2)	3	0.24	3	(0.2)	3	0.20
Arthropod sting	3	(0.2)	3	0.20	1	(0.1)	1	0.09
Upper limb fracture	3	(0.2)	3	0.15	0			
Medication error	2	(0.1)	2	0.18	2	(0.1)	2	0.18
Fibula fracture	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Injury	2	(0.1)	2	0.11	0			
Meniscus injury	2	(0.1)	2	0.11	5	(0.3)	5	0.30
Tendon rupture	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Hip fracture	2	(0.1)	2	0.11	0			
Radius fracture	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Back injury	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Craniocerebral injury	1	(0.1)	1	0.09	0			
Face injury	1	(0.1)	1	0.09	0			
Facial bones fracture	1	(0.1)	1	0.09	0			
Subcutaneous haematoma	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Underdose	1	(0.1)	1	0.09	5	(0.3)	5	0.42
Wrist fracture	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Gun shot wound	1	(0.1)	1	0.09	0			
Ligament rupture	1	(0.1)	2	0.18	0			
Procedural complication	1	(0.1)	1	0.09	0			
Accidental underdose	1	(0.1)	1	0.09	0			
Chillblains	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Extra dose administered	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Subdural haematoma	1	(0.1)	1	0.09	0			
Wrong product administered	1	(0.1)	2	0.19	2	(0.1)	2	0.18
Burn oral cavity	1	(0.1)	1	0.05	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Burns first degree	1	(0.1)	1	0.05	0			
Cervical vertebral fracture	1	(0.1)	1	0.05	0			
Eye injury	1	(0.1)	1	0.05	0			
Heat illness	1	(0.1)	1	0.05	3	(0.2)	4	0.25
Muscle strain	1	(0.1)	1	0.05	4	(0.2)	4	0.29
Post procedural fistula	1	(0.1)	1	0.05	0			
Post procedural haemorrhage	1	(0.1)	1	0.05	0			
Post procedural hypothyroidism	1	(0.1)	1	0.05	0			
Scar	1	(0.1)	1	0.05	0			
Traumatic haematoma	1	(0.1)	1	0.05	0			
Animal bite	1	(0.1)	1	0.05	3	(0.2)	3	0.20
Bone contusion	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Femoral neck fracture	1	(0.1)	1	0.05	0			
Inflammation of wound	1	(0.1)	1	0.05	0			
Injury of conjunctiva	1	(0.1)	1	0.05	0			
Multiple injuries	1	(0.1)	1	0.05	0			
Muscle injury	1	(0.1)	1	0.05	2	(0.1)	2	0.18
Neck injury	1	(0.1)	1	0.05	0			
Penile contusion	1	(0.1)	1	0.05	0			
Post procedural complication	1	(0.1)	1	0.05	0			
Post procedural haematuria	1	(0.1)	1	0.05	0			
Post procedural inflammation	1	(0.1)	1	0.05	0			
Radiation skin injury	1	(0.1)	1	0.05	0			
Spinal compression fracture	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Product administration error	0				2	(0.1)	2	0.14
Soft tissue injury	0				2	(0.1)	2	0.11
Concussion	0				2	(0.1)	2	0.19
Wrong dose	0				2	(0.1)	2	0.18
Epicondylitis	0				1	(0.1)	1	0.05
Head injury	0				1	(0.1)	1	0.05
Humerus fracture	0				1	(0.1)	1	0.05
Periprocedural myocardial infarction	0				1	(0.1)	1	0.05
Scratch	0				1	(0.1)	1	0.05
Sunburn	0				1	(0.1)	1	0.05
Crush injury	0				1	(0.1)	1	0.09
Exposure to SARS-CoV-2	0				1	(0.1)	1	0.09
Spinal column injury	0				1	(0.1)	1	0.09
Deafness traumatic	0				1	(0.1)	1	0.05
Endotracheal intubation complication	0				1	(0.1)	1	0.05
Lower limb fracture	0				1	(0.1)	1	0.05
Post procedural stroke	0				1	(0.1)	1	0.05
Post procedural swelling	0				1	(0.1)	2	0.11
Intentional product use issue	0				1	(0.1)	1	0.09
Post-traumatic neck syndrome	0				1	(0.1)	1	0.09
Seroma	0				1	(0.1)	1	0.09
Intentional overdose	0				1	(0.1)	1	0.09
Muscle contusion	0				1	(0.1)	1	0.09
Stab wound	0				1	(0.1)	1	0.09
Tendon injury	0				1	(0.1)	1	0.09
Tibia fracture	0				1	(0.1)	1	0.09
Eye disorders	147	(7.8)	188	13.62	152	(8.1)	199	14.86
Diabetic retinopathy	52	(2.8)	58	4.63	58	(3.1)	62	4.78
Cataract	24	(1.3)	29	1.84	25	(1.3)	28	1.90

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Macular oedema	9	(0.5)	9	0.71	4	(0.2)	4	0.25
Retinopathy hypertensive	6	(0.3)	7	0.52	5	(0.3)	5	0.42
Dry eye	6	(0.3)	6	0.35	6	(0.3)	6	0.36
Blepharitis	5	(0.3)	5	0.30	0			
Diabetic retinal oedema	4	(0.2)	4	0.37	9	(0.5)	10	0.76
Vision blurred	4	(0.2)	4	0.29	5	(0.3)	5	0.34
Retinal haemorrhage	4	(0.2)	4	0.33	0			
Eye pain	4	(0.2)	4	0.25	3	(0.2)	3	0.20
Vitreous detachment	3	(0.2)	3	0.20	0			
Glaucoma	3	(0.2)	3	0.15	3	(0.2)	3	0.20
Ocular hyperaemia	2	(0.1)	3	0.27	1	(0.1)	2	0.18
Vitreous haemorrhage	2	(0.1)	2	0.18	2	(0.1)	2	0.15
Conjunctival haemorrhage	2	(0.1)	2	0.14	0			
Conjunctivitis allergic	2	(0.1)	3	0.20	0			
Eye inflammation	2	(0.1)	2	0.15	2	(0.1)	2	0.19
Diplopia	2	(0.1)	2	0.15	1	(0.1)	1	0.09
Ocular hypertension	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Age-related macular degeneration	2	(0.1)	2	0.14	0			
Astigmatism	2	(0.1)	3	0.16	4	(0.2)	4	0.29
Cataract nuclear	1	(0.1)	1	0.09	0			
Dry age-related macular degeneration	1	(0.1)	1	0.09	0			
Epiretinal membrane	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Eye irritation	1	(0.1)	1	0.09	0			
Lacrimation increased	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Myopia	1	(0.1)	1	0.09	2	(0.1)	2	0.10
Retinal exudates	1	(0.1)	1	0.09	2	(0.1)	2	0.19
Retinal vein occlusion	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Non-proliferative retinopathy	1	(0.1)	2	0.18	2	(0.1)	2	0.18
Presbyopia	1	(0.1)	1	0.09	2	(0.1)	2	0.18
Retinal deposits	1	(0.1)	1	0.09	0			
Retinal drusen	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Retinal scar	1	(0.1)	1	0.09	0			
Acquired epiblepharon	1	(0.1)	1	0.05	0			
Asthenopia	1	(0.1)	1	0.05	0			
Conjunctival erosion	1	(0.1)	1	0.05	0			
Optic disc vascular disorder	1	(0.1)	1	0.05	0			
Post thrombotic retinopathy	1	(0.1)	1	0.05	0			
Posterior capsule opacification	1	(0.1)	1	0.05	0			
Retinal aneurysm	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Retinal tear	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Amaurosis fugax	1	(0.1)	1	0.05	0			
Angle closure glaucoma	1	(0.1)	1	0.05	0			
Arteriosclerotic retinopathy	1	(0.1)	1	0.05	0			
Conjunctival hyperaemia	1	(0.1)	1	0.05	0			
Conjunctival suffusion	1	(0.1)	1	0.05	0			
Maculopathy	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Retinal degeneration	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Visual impairment	1	(0.1)	1	0.05	2	(0.1)	10	0.89
Vitreous opacities	1	(0.1)	1	0.05	0			
Macular degeneration	0				3	(0.2)	3	0.20
Retinal artery occlusion	0				2	(0.1)	2	0.11
Eye discharge	0				2	(0.1)	2	0.15
Retinal detachment	0				2	(0.1)	2	0.15
Cystoid macular oedema	0				1	(0.1)	1	0.05

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Eyelid oedema	0				1	(0.1)	1	0.05
Hypermetropia	0				1	(0.1)	1	0.05
Ocular ischaemic syndrome	0				1	(0.1)	1	0.05
Ophthalmic vein thrombosis	0				1	(0.1)	1	0.05
Corneal erosion	0				1	(0.1)	1	0.09
Meibomianitis	0				1	(0.1)	1	0.09
Open angle glaucoma	0				1	(0.1)	2	0.19
Retinal vascular disorder	0				1	(0.1)	1	0.09
Dacryoadenitis acquired	0				1	(0.1)	1	0.05
Normal tension glaucoma	0				1	(0.1)	1	0.05
Photophobia	0				1	(0.1)	1	0.05
Scintillating scotoma	0				1	(0.1)	1	0.05
Uveitis	0				1	(0.1)	1	0.05
Chorioretinal atrophy	0				1	(0.1)	1	0.09
Corneal bleeding	0				1	(0.1)	1	0.09
Eye pruritus	0				1	(0.1)	2	0.18
Macular hole	0				1	(0.1)	1	0.09
Optic disc haemorrhage	0				1	(0.1)	1	0.09
Retinopathy	0				1	(0.1)	1	0.09
Vitreous degeneration	0				1	(0.1)	1	0.09
Vitreous floaters	0				1	(0.1)	1	0.09
Visual acuity reduced	0				1	(0.1)	1	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Metabolism and nutrition disorders	124	(6.6)	153	10.03	125	(6.7)	158	10.78
Dyslipidaemia	21	(1.1)	22	1.56	17	(0.9)	17	1.33
Vitamin D deficiency	16	(0.8)	16	0.87	12	(0.6)	12	0.70
Hyperlipidaemia	14	(0.7)	14	0.93	13	(0.7)	13	0.84
Hypoglycaemia	13	(0.7)	19	1.51	20	(1.1)	36	2.46
Vitamin B12 deficiency	11	(0.6)	11	0.56	1	(0.1)	1	0.05
Hypertriglyceridaemia	10	(0.5)	10	0.65	8	(0.4)	8	0.58
Hyperkalaemia	8	(0.4)	9	0.59	10	(0.5)	10	0.73
Hyperglycaemia	6	(0.3)	7	0.56	14	(0.7)	14	1.06
Iron deficiency	5	(0.3)	5	0.26	3	(0.2)	3	0.15
Decreased appetite	4	(0.2)	4	0.25	5	(0.3)	5	0.30
Gout	4	(0.2)	5	0.26	6	(0.3)	7	0.37
Hypercholesterolaemia	3	(0.2)	3	0.24	3	(0.2)	3	0.24
Increased appetite	3	(0.2)	3	0.16	6	(0.3)	7	0.56
Hyperuricaemia	3	(0.2)	3	0.19	3	(0.2)	3	0.16
Hyponatraemia	2	(0.1)	2	0.19	1	(0.1)	1	0.09
Fluid retention	2	(0.1)	2	0.15	0			
Hypokalaemia	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Dehydration	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Zinc deficiency	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Diabetes mellitus	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Folate deficiency	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Abnormal weight gain	1	(0.1)	1	0.09	0			
Hypoalbuminaemia	1	(0.1)	1	0.09	0			
Obesity	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Diabetes mellitus inadequate control	1	(0.1)	1	0.05	0			
Hypernatraemia	1	(0.1)	1	0.05	0			
Magnesium deficiency	1	(0.1)	1	0.05	0			
Malnutrition	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Vitamin B complex deficiency	1	(0.1)	1	0.05	0			
Hypercalcaemia	0				1	(0.1)	1	0.05
Insulin resistance	0				1	(0.1)	1	0.05
Lactic acidosis	0				1	(0.1)	1	0.05
Lipomatosis	0				1	(0.1)	1	0.09
Appetite disorder	0				1	(0.1)	2	0.11
Electrolyte imbalance	0				1	(0.1)	1	0.05
Metabolic disorder	0				1	(0.1)	1	0.05
Food craving	0				1	(0.1)	1	0.09
Metabolic acidosis	0				1	(0.1)	1	0.09
Hyperammonaemia	0				1	(0.1)	1	0.09
Respiratory, thoracic and mediastinal disorders	111	(5.9)	151	10.45	101	(5.4)	124	8.54
Cough	23	(1.2)	24	1.62	20	(1.1)	21	1.39
Oropharyngeal pain	19	(1.0)	21	1.31	16	(0.9)	18	1.31
Rhinorrhoea	10	(0.5)	13	0.95	7	(0.4)	7	0.45
Nasal congestion	10	(0.5)	10	0.61	4	(0.2)	4	0.21
Dyspnoea	9	(0.5)	9	0.66	13	(0.7)	14	0.98
Sleep apnoea syndrome	7	(0.4)	7	0.45	0			
Epistaxis	5	(0.3)	9	0.81	2	(0.1)	4	0.29
Asthma	5	(0.3)	6	0.44	1	(0.1)	1	0.09
Chronic obstructive pulmonary disease	4	(0.2)	4	0.33	1	(0.1)	1	0.05
Productive cough	4	(0.2)	4	0.29	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. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Respiratory disorder	4	(0.2)	4	0.33	5	(0.3)	5	0.35
Sinus congestion	4	(0.2)	5	0.34	1	(0.1)	1	0.05
Acute respiratory failure	3	(0.2)	3	0.20	1	(0.1)	1	0.05
Nasal septum deviation	2	(0.1)	2	0.18	1	(0.1)	1	0.09
Sneezing	2	(0.1)	2	0.14	0			
Emphysema	2	(0.1)	2	0.15	2	(0.1)	2	0.15
Pulmonary fibrosis	2	(0.1)	3	0.20	0			
Sinus pain	2	(0.1)	3	0.20	1	(0.1)	1	0.09
Interstitial lung disease	2	(0.1)	2	0.11	0			
Nasal obstruction	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Respiratory failure	1	(0.1)	1	0.09	2	(0.1)	2	0.11
Bronchospasm	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Pleurisy	1	(0.1)	1	0.09	0			
Pulmonary hypertension	1	(0.1)	1	0.09	0			
Acquired diaphragmatic eventration	1	(0.1)	1	0.05	0			
Bronchiectasis	1	(0.1)	1	0.05	0			
Dyspnoea exertional	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Laryngeal cyst	1	(0.1)	1	0.05	0			
Nasal dryness	1	(0.1)	1	0.05	0			
Nasal turbinate hypertrophy	1	(0.1)	1	0.05	0			
Pulmonary embolism	1	(0.1)	1	0.05	0			
Pulmonary mass	1	(0.1)	1	0.05	4	(0.2)	4	0.29
Throat irritation	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Upper-airway cough syndrome	1	(0.1)	1	0.05	0			
Increased viscosity of upper respiratory secretion	1	(0.1)	1	0.05	0			
Rhinitis allergic	1	(0.1)	1	0.05	5	(0.3)	9	0.64
Upper respiratory tract inflammation	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Pleural effusion	0				3	(0.2)	3	0.16
Paranasal cyst	0				2	(0.1)	2	0.19
Bronchitis chronic	0				2	(0.1)	2	0.15
Aphonia	0				1	(0.1)	1	0.05
Respiratory tract inflammation	0				1	(0.1)	1	0.05
Acute pulmonary oedema	0				1	(0.1)	1	0.05
Allergic bronchitis	0				1	(0.1)	1	0.05
Haemoptysis	0				1	(0.1)	1	0.05
Paranasal sinus discomfort	0				1	(0.1)	1	0.05
Pleuritic pain	0				1	(0.1)	1	0.05
Allergic cough	0				1	(0.1)	1	0.09
Dry throat	0				1	(0.1)	1	0.09
Dysphonia	0				1	(0.1)	2	0.18
Lung disorder	0				1	(0.1)	1	0.09
Pleural disorder	0				1	(0.1)	1	0.09
Skin and subcutaneous tissue disorders	99	(5.3)	107	7.16	104	(5.5)	123	8.08
Rash	11	(0.6)	11	0.77	11	(0.6)	12	0.71
Eczema	10	(0.5)	10	0.65	6	(0.3)	6	0.47
Hyperhidrosis	8	(0.4)	8	0.58	5	(0.3)	5	0.34
Pruritus	8	(0.4)	8	0.54	11	(0.6)	11	0.78
Urticaria	7	(0.4)	7	0.52	9	(0.5)	9	0.51
Alopecia	5	(0.3)	5	0.34	3	(0.2)	3	0.20
Dermatitis contact	5	(0.3)	6	0.32	8	(0.4)	8	0.51
Cold sweat	4	(0.2)	4	0.29	3	(0.2)	3	0.20
Skin ulcer	4	(0.2)	4	0.29	5	(0.3)	5	0.42

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Adverse events by system organ class and preferred term - on-treatment/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 skin	3	(0.2)	3	0.16	4	(0.2)	4	0.25
Dermatitis	3	(0.2)	3	0.20	6	(0.3)	7	0.49
Night sweats	3	(0.2)	3	0.20	0			
Miliaria	2	(0.1)	2	0.18	4	(0.2)	4	0.22
Hyperkeratosis	2	(0.1)	2	0.15	1	(0.1)	1	0.09
Psoriasis	2	(0.1)	2	0.11	2	(0.1)	2	0.14
Skin irritation	2	(0.1)	3	0.16	2	(0.1)	2	0.10
Acne	2	(0.1)	2	0.14	0			
Dermatitis allergic	2	(0.1)	2	0.11	1	(0.1)	1	0.09
Ingrowing nail	2	(0.1)	2	0.11	3	(0.2)	3	0.16
Blister	1	(0.1)	1	0.09	2	(0.1)	2	0.15
Rash papular	1	(0.1)	1	0.09	0			
Decubitus ulcer	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Ecchymosis	1	(0.1)	1	0.09	2	(0.1)	2	0.11
Rash erythematous	1	(0.1)	1	0.09	0			
Skin odour abnormal	1	(0.1)	1	0.09	0			
Intertrigo	1	(0.1)	1	0.09	0			
Umbilical haematoma	1	(0.1)	1	0.09	0			
Angioedema	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Granuloma annulare	1	(0.1)	1	0.05	0			
Lipodystrophy acquired	1	(0.1)	1	0.05	0			
Myxoid cyst	1	(0.1)	1	0.05	0			
Skin exfoliation	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Skin fissures	1	(0.1)	1	0.05	0			
Skin lesion	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Urticaria contact	1	(0.1)	1	0.05	0			
Diabetic foot	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Erythema	1	(0.1)	1	0.05	3	(0.2)	3	0.20
Livedo reticularis	1	(0.1)	1	0.05	0			
Nail bed inflammation	1	(0.1)	1	0.05	0			
Dermal cyst	0				3	(0.2)	3	0.20
Lipohypertrophy	0				2	(0.1)	2	0.15
Hidradenitis	0				1	(0.1)	1	0.05
Seborrhoea	0				1	(0.1)	1	0.09
Skin reaction	0				1	(0.1)	1	0.09
Actinic keratosis	0				1	(0.1)	1	0.05
Alopecia areata	0				1	(0.1)	1	0.05
Asteatosis	0				1	(0.1)	1	0.05
Cold urticaria	0				1	(0.1)	1	0.05
Drug eruption	0				1	(0.1)	1	0.05
Haemorrhage subcutaneous	0				1	(0.1)	1	0.05
Lentigo	0				1	(0.1)	1	0.05
Macule	0				1	(0.1)	1	0.05
Purpura	0				1	(0.1)	1	0.05
Urticaria thermal	0				1	(0.1)	1	0.05
Leukoplakia	0				1	(0.1)	1	0.09
Pruritus allergic	0				1	(0.1)	1	0.09
Rash maculo-papular	0				1	(0.1)	1	0.09
Skin discolouration	0				1	(0.1)	1	0.09
Neurodermatitis	0				1	(0.1)	1	0.09
Cardiac disorders	86	(4.6)	124	7.61	79	(4.2)	109	6.93
Atrial fibrillation	12	(0.6)	13	0.73	6	(0.3)	6	0.36
Coronary artery disease	12	(0.6)	12	0.71	10	(0.5)	10	0.60

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Adverse events by system organ class and preferred term - on-treatment/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 myocardial infarction	9	(0.5)	9	0.59	8	(0.4)	8	0.54
Cardiac failure	8	(0.4)	8	0.46	2	(0.1)	3	0.24
Myocardial infarction	6	(0.3)	6	0.44	4	(0.2)	4	0.21
Palpitations	6	(0.3)	6	0.36	5	(0.3)	5	0.31
Angina pectoris	6	(0.3)	6	0.35	4	(0.2)	4	0.25
Ventricular extrasystoles	5	(0.3)	5	0.27	2	(0.1)	3	0.16
Cardiac failure congestive	4	(0.2)	4	0.25	2	(0.1)	3	0.28
Acute coronary syndrome	4	(0.2)	4	0.21	0			
Supraventricular extrasystoles	3	(0.2)	3	0.24	2	(0.1)	2	0.11
Myocardial ischaemia	3	(0.2)	3	0.24	2	(0.1)	2	0.11
Angina unstable	3	(0.2)	3	0.16	1	(0.1)	1	0.05
Mitral valve incompetence	3	(0.2)	3	0.20	2	(0.1)	2	0.10
Left ventricular hypertrophy	3	(0.2)	3	0.16	2	(0.1)	2	0.15
Tachycardia	3	(0.2)	3	0.15	7	(0.4)	7	0.48
Left ventricular dysfunction	2	(0.1)	2	0.15	2	(0.1)	2	0.15
Cardiac failure chronic	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Coronary artery occlusion	2	(0.1)	2	0.11	0			
Supraventricular tachycardia	2	(0.1)	2	0.14	0			
Atrioventricular block first degree	2	(0.1)	2	0.14	0			
Bundle branch block left	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Arrhythmia	2	(0.1)	2	0.10	3	(0.2)	3	0.20
Cardiac flutter	1	(0.1)	1	0.09	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Mitral valve stenosis	1	(0.1)	1	0.09	0			
Aortic valve sclerosis	1	(0.1)	1	0.09	0			
Left atrial enlargement	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Aortic valve incompetence	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Atrial flutter	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Atrial thrombosis	1	(0.1)	1	0.05	0			
Bradycardia	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Bundle branch block right	1	(0.1)	1	0.05	6	(0.3)	7	0.45
Cardiac ventricular thrombosis	1	(0.1)	1	0.05	0			
Chronic coronary syndrome	1	(0.1)	1	0.05	0			
Diastolic dysfunction	1	(0.1)	1	0.05	0			
Left atrial dilatation	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Pericardial effusion	1	(0.1)	1	0.05	0			
Pericarditis	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Sinus tachycardia	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Tricuspid valve incompetence	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Arteriosclerosis coronary artery	1	(0.1)	1	0.05	0			
Sinus bradycardia	0				3	(0.2)	3	0.20
Cardiac arrest	0				2	(0.1)	2	0.10
Subendocardial ischaemia	0				2	(0.1)	2	0.10
Aortic valve calcification	0				2	(0.1)	2	0.15
Cardiac failure acute	0				1	(0.1)	1	0.05
Coronary artery stenosis	0				1	(0.1)	1	0.05
Ventricular arrhythmia	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrial enlargement	0				1	(0.1)	1	0.09
Cardiac perfusion defect	0				1	(0.1)	2	0.19
Atrioventricular block complete	0				1	(0.1)	1	0.05
Cardiac dysfunction	0				1	(0.1)	1	0.05
Sinus arrhythmia	0				1	(0.1)	1	0.05

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Investigations	80	(4.3)	94	6.46	66	(3.5)	73	5.06
Weight increased	19	(1.0)	19	1.32	18	(1.0)	18	1.24
Blood creatinine increased	8	(0.4)	8	0.65	0			
SARS-CoV-2 test positive	7	(0.4)	7	0.56	0			
Alanine aminotransferase increased	4	(0.2)	4	0.33	0			
Weight decreased	4	(0.2)	4	0.21	1	(0.1)	1	0.05
Blood alkaline phosphatase increased	3	(0.2)	3	0.28	0			
Blood pressure increased	3	(0.2)	3	0.20	4	(0.2)	4	0.25
Liver function test increased	3	(0.2)	3	0.24	1	(0.1)	1	0.05
Blood triglycerides increased	3	(0.2)	3	0.20	3	(0.2)	3	0.16
Blood immunoglobulin E increased	3	(0.2)	3	0.15	3	(0.2)	3	0.15
Blood cholesterol increased	2	(0.1)	2	0.11	0			
Occult blood	2	(0.1)	2	0.14	0			
Prostatic specific antigen increased	2	(0.1)	2	0.10	0			
Arthroscopy	1	(0.1)	1	0.09	0			
Aspartate aminotransferase increased	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Blood glucose fluctuation	1	(0.1)	1	0.09	0			
Blood potassium increased	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Monocyte count decreased	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Monofilament pressure perception test	1	(0.1)	1	0.09	0			
Catheterisation cardiac	1	(0.1)	1	0.09	0			
Eosinophil count increased	1	(0.1)	1	0.09	0			
Liver function test abnormal	1	(0.1)	1	0.09	1	(0.1)	2	0.18
Blood creatine increased	1	(0.1)	1	0.05	0			
Blood creatine phosphokinase increased	1	(0.1)	1	0.05	0			
Body temperature increased	1	(0.1)	1	0.05	0			
Glycosylated haemoglobin increased	1	(0.1)	1	0.05	2	(0.1)	3	0.15
International normalised ratio abnormal	1	(0.1)	1	0.05	0			
International normalised ratio decreased	1	(0.1)	1	0.05	0			
International normalised ratio increased	1	(0.1)	2	0.11	0			
Red blood cell count decreased	1	(0.1)	1	0.05	0			
Transferrin saturation decreased	1	(0.1)	1	0.05	0			
Blood urine present	1	(0.1)	3	0.15	1	(0.1)	1	0.09
Bone density decreased	1	(0.1)	1	0.05	0			
Electrocardiogram abnormal	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Electrocardiogram ST segment abnormal	1	(0.1)	1	0.05	0			
Electrocardiogram T wave inversion	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Hepatic enzyme increased	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Low density lipoprotein increased	1	(0.1)	1	0.05	2	(0.1)	2	0.18
QRS axis abnormal	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Thyroid function test abnormal	1	(0.1)	1	0.05	0			
Transaminases increased	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Platelet count decreased	0				3	(0.2)	3	0.28
Antinuclear antibody positive	0				1	(0.1)	1	0.05
Breath sounds abnormal	0				1	(0.1)	1	0.05
Carbohydrate antigen 19-9 increased	0				1	(0.1)	1	0.05
Cardiac murmur	0				1	(0.1)	1	0.05
Ejection fraction decreased	0				1	(0.1)	1	0.05
Grip strength decreased	0				1	(0.1)	1	0.05
Lipase increased	0				1	(0.1)	1	0.05
Vitamin D decreased	0				1	(0.1)	1	0.05
Amylase increased	0				1	(0.1)	1	0.09
Glomerular filtration rate decreased	0				1	(0.1)	1	0.09
Haematocrit increased	0				1	(0.1)	1	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Haemoglobin increased	0				1	(0.1)	1	0.09
Blood glucose increased	0				1	(0.1)	1	0.05
Blood pressure decreased	0				1	(0.1)	1	0.05
Cardiac stress test abnormal	0				1	(0.1)	1	0.05
Electrocardiogram repolarisation abnormality	0				1	(0.1)	1	0.05
Haemoglobin decreased	0				1	(0.1)	1	0.05
Lipids increased	0				1	(0.1)	1	0.05
Blood glucose decreased	0				1	(0.1)	1	0.09
Electrocardiogram P wave biphasic	0				1	(0.1)	1	0.09
Electrocardiogram ST segment depression	0				1	(0.1)	1	0.09
Free fatty acids increased	0				1	(0.1)	1	0.09
Intraocular pressure increased	0				1	(0.1)	1	0.09
Vascular disorders	73	(3.9)	82	5.47	76	(4.0)	95	6.58
Hypertension	32	(1.7)	32	2.19	35	(1.9)	40	2.81
Hypotension	6	(0.3)	6	0.40	3	(0.2)	3	0.20
Peripheral arterial occlusive disease	4	(0.2)	5	0.34	2	(0.1)	2	0.11
Peripheral coldness	3	(0.2)	3	0.16	1	(0.1)	1	0.05
Arteriosclerosis	3	(0.2)	3	0.16	7	(0.4)	7	0.49
Superficial vein thrombosis	3	(0.2)	3	0.16	0			
Orthostatic hypotension	2	(0.1)	2	0.18	0			
Haematoma	2	(0.1)	2	0.15	3	(0.2)	3	0.24
Peripheral artery stenosis	2	(0.1)	5	0.39	0			
Peripheral venous disease	2	(0.1)	2	0.15	3	(0.2)	3	0.20
Aortic arteriosclerosis	2	(0.1)	2	0.11	4	(0.2)	4	0.33
Blood pressure inadequately controlled	2	(0.1)	2	0.10	2	(0.1)	2	0.11
Arterial insufficiency	1	(0.1)	1	0.09	0			
Varicose ulceration	1	(0.1)	1	0.09	0			
Deep vein thrombosis	1	(0.1)	1	0.09	0			
Diabetic vascular disorder	1	(0.1)	1	0.09	2	(0.1)	2	0.18
Hypertensive crisis	1	(0.1)	1	0.09	2	(0.1)	4	0.33
Aortic stenosis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Brachiocephalic arteriosclerosis	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Flushing	1	(0.1)	1	0.05	0			
Hypertensive urgency	1	(0.1)	1	0.05	2	(0.1)	3	0.20
Peripheral artery occlusion	1	(0.1)	1	0.05	0			
Peripheral vascular disorder	1	(0.1)	1	0.05	0			
Thrombosis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Varicose vein	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Hot flush	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Venous stenosis	1	(0.1)	1	0.05	0			
Intermittent claudication	0				2	(0.1)	2	0.11
Aneurysm	0				1	(0.1)	1	0.05
Aortic aneurysm	0				1	(0.1)	1	0.05
Peripheral ischaemia	0				1	(0.1)	1	0.05
Phlebitis	0				1	(0.1)	1	0.05
Blood pressure fluctuation	0				1	(0.1)	1	0.09
Neovascularisation	0				1	(0.1)	1	0.09
Thrombophlebitis	0				1	(0.1)	1	0.09
Iliac artery stenosis	0				1	(0.1)	1	0.05
Macroangiopathy	0				1	(0.1)	1	0.05
Aortic dilatation	0				1	(0.1)	1	0.09
Peripheral artery aneurysm	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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Renal and urinary disorders	51	(2.7)	62	4.34	51	(2.7)	64	4.03
Renal cyst	7	(0.4)	7	0.52	4	(0.2)	4	0.25
Pollakiuria	5	(0.3)	5	0.42	2	(0.1)	2	0.11
Nephrolithiasis	5	(0.3)	5	0.26	4	(0.2)	6	0.43
Renal impairment	4	(0.2)	4	0.29	3	(0.2)	3	0.16
Chronic kidney disease	4	(0.2)	4	0.33	5	(0.3)	5	0.30
Dysuria	4	(0.2)	5	0.30	4	(0.2)	4	0.25
Diabetic nephropathy	3	(0.2)	3	0.20	2	(0.1)	2	0.18
Acute kidney injury	3	(0.2)	3	0.24	5	(0.3)	5	0.26
Ureterolithiasis	3	(0.2)	3	0.20	3	(0.2)	3	0.16
Urine odour abnormal	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Nocturia	2	(0.1)	2	0.11	2	(0.1)	2	0.11
Bladder prolapse	1	(0.1)	1	0.09	0			
Hydronephrosis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Nephrotic syndrome	1	(0.1)	1	0.09	0			
Polyuria	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Urethral stenosis	1	(0.1)	1	0.09	0			
Chromaturia	1	(0.1)	1	0.09	0			
Renal failure	1	(0.1)	1	0.09	0			
Haematuria	1	(0.1)	2	0.19	5	(0.3)	5	0.30
Calculus urinary	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Microalbuminuria	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Pyelocaliectasis	1	(0.1)	1	0.05	0			
Renal colic	1	(0.1)	1	0.05	3	(0.2)	3	0.24
Hypertonic bladder	1	(0.1)	1	0.05	0			
Proteinuria	1	(0.1)	1	0.05	0			
Renal pain	1	(0.1)	1	0.05	0			
Urinary incontinence	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Urinary retention	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Urinary tract disorder	1	(0.1)	1	0.05	0			
Bladder mass	0				1	(0.1)	1	0.05
Cystitis haemorrhagic	0				1	(0.1)	1	0.05
Renal mass	0				1	(0.1)	1	0.05
Stress urinary incontinence	0				1	(0.1)	1	0.05
Urinary tract inflammation	0				1	(0.1)	1	0.05
Hydrocalyx	0				1	(0.1)	1	0.09
Nephropathy	0				1	(0.1)	1	0.09
Urinary tract obstruction	0				1	(0.1)	1	0.05
Micturition urgency	0				1	(0.1)	1	0.09
Strangury	0				1	(0.1)	1	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Psychiatric disorders	36	(1.9)	40	2.57	37	(2.0)	39	2.80
Insomnia	10	(0.5)	10	0.68	6	(0.3)	7	0.49
Depression	8	(0.4)	8	0.50	9	(0.5)	9	0.63
Anxiety	5	(0.3)	5	0.30	6	(0.3)	6	0.31
Sleep disorder	4	(0.2)	4	0.21	4	(0.2)	4	0.37
Irritability	2	(0.1)	2	0.14	0			
Adjustment disorder	1	(0.1)	1	0.09	0			
Agitation	1	(0.1)	1	0.09	0			
Drug abuse	1	(0.1)	1	0.09	0			
Mental status changes	1	(0.1)	1	0.09	0			
Depressed mood	1	(0.1)	1	0.05	0			
Nightmare	1	(0.1)	1	0.05	0			
Adjustment disorder with mixed anxiety and depressed mood	1	(0.1)	1	0.05	0			
Disorientation	1	(0.1)	1	0.05	0			
Listless	1	(0.1)	1	0.05	0			
Post-traumatic stress disorder	1	(0.1)	1	0.05	0			
Stress	1	(0.1)	1	0.05	0			
Fear	0				2	(0.1)	2	0.19
Anxiety disorder	0				1	(0.1)	1	0.05
Drug dependence	0				1	(0.1)	1	0.05
Affect lability	0				1	(0.1)	1	0.09
Mixed anxiety and depressive disorder	0				1	(0.1)	1	0.09
Phobia	0				1	(0.1)	1	0.09
Bruxism	0				1	(0.1)	1	0.05
Mood swings	0				1	(0.1)	1	0.05
Persistent depressive disorder	0				1	(0.1)	1	0.05
Adjustment disorder with depressed mood	0				1	(0.1)	1	0.09
Emotional distress	0				1	(0.1)	1	0.09
Major depression	0				1	(0.1)	1	0.09
Blood and lymphatic system disorders	33	(1.8)	35	2.47	30	(1.6)	30	1.98
Anaemia	19	(1.0)	21	1.53	14	(0.7)	14	0.94
Eosinophilia	3	(0.2)	3	0.20	2	(0.1)	2	0.15
Iron deficiency anaemia	2	(0.1)	2	0.15	3	(0.2)	3	0.20
Lymphadenopathy	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Leukopenia	1	(0.1)	1	0.09	0			
Blood loss anaemia	1	(0.1)	1	0.09	2	(0.1)	2	0.11
Lymphadenopathy mediastinal	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Polycythaemia	1	(0.1)	1	0.05	0			
Thrombocytopenia	1	(0.1)	1	0.05	0			
Leukocytosis	1	(0.1)	1	0.05	3	(0.2)	3	0.15
Splenomegaly	1	(0.1)	1	0.05	0			
Pancytopenia	0				1	(0.1)	1	0.05
Hypochromic anaemia	0				1	(0.1)	1	0.05
Normocytic anaemia	0				1	(0.1)	1	0.09
Thrombocytosis	0				1	(0.1)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	31	(1.6)	39	2.56	27	(1.4)	40	2.56
Colon adenoma	3	(0.2)	3	0.23	0			
Pancreatic neoplasm	2	(0.1)	2	0.15	0			
Seborrhoeic keratosis	2	(0.1)	3	0.16	0			

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Colorectal cancer	2	(0.1)	2	0.14	0			
Eye naevus	2	(0.1)	3	0.20	0			
Metastases to liver	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Gastric cancer	1	(0.1)	1	0.09	0			
Bladder papilloma	1	(0.1)	1	0.09	0			
Lung cancer metastatic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Skin papilloma	1	(0.1)	1	0.09	0			
Osteoma	1	(0.1)	1	0.09	0			
Small cell lung cancer	1	(0.1)	1	0.09	0			
Acrochordon	1	(0.1)	1	0.05	0			
Basal cell carcinoma	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Haemangioma of liver	1	(0.1)	1	0.05	0			
Neoplasm skin	1	(0.1)	1	0.05	0			
Oral fibroma	1	(0.1)	1	0.05	0			
Prostate cancer	1	(0.1)	1	0.05	0			
Salivary gland neoplasm	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Invasive ductal breast carcinoma	1	(0.1)	1	0.05	0			
Invasive lobular breast carcinoma	1	(0.1)	1	0.05	0			
Lipoma	1	(0.1)	1	0.05	0			
Pancreatic carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Renal neoplasm	1	(0.1)	1	0.05	0			
Squamous cell carcinoma of skin	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Uterine leiomyoma	0				3	(0.2)	3	0.20
Adrenal adenoma	0				2	(0.1)	2	0.18
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Benign renal neoplasm	0				1	(0.1)	1	0.05
Bowen's disease	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Gastrointestinal tract adenoma	0				1	(0.1)	1	0.05
Invasive breast carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma	0				1	(0.1)	1	0.05
Malignant peritoneal neoplasm	0				1	(0.1)	1	0.05
Metastases to bone marrow	0				1	(0.1)	1	0.05
Metastases to lymph nodes	0				1	(0.1)	1	0.05
Myxoma	0				1	(0.1)	1	0.05
Prostatic adenoma	0				1	(0.1)	1	0.05
Renal hamartoma	0				1	(0.1)	1	0.05
Small intestine neuroendocrine tumour	0				1	(0.1)	1	0.09
Uterine cancer	0				1	(0.1)	1	0.09
Colon cancer	0				1	(0.1)	1	0.05
Dysplastic naevus	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma in situ	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Breast cancer	0				1	(0.1)	1	0.09
Colon cancer stage II	0				1	(0.1)	1	0.09
Lymphangioma	0				1	(0.1)	1	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Reproductive system and breast disorders	29	(1.5)	29	1.91	23	(1.2)	27	1.65
Benign prostatic hyperplasia	5	(0.3)	5	0.34	3	(0.2)	3	0.20
Erectile dysfunction	5	(0.3)	5	0.30	1	(0.1)	1	0.09
Intermenstrual bleeding	2	(0.1)	2	0.18	0			
Uterine polyp	2	(0.1)	2	0.11	0			
Cervical polyp	1	(0.1)	1	0.09	0			
Prostatitis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Breast pain	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Menstruation delayed	1	(0.1)	1	0.09	0			
Prostatic calcification	1	(0.1)	1	0.09	0			
Breast mass	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Menopausal symptoms	1	(0.1)	1	0.05	0			
Ovarian cyst	1	(0.1)	1	0.05	0			
Pruritus genital	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Uterine prolapse	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Vulvovaginal pruritus	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Atrophic vulvovaginitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Ejaculation failure	1	(0.1)	1	0.05	0			
Menstruation irregular	1	(0.1)	1	0.05	0			
Pelvic discomfort	1	(0.1)	1	0.05	0			
Vaginal haemorrhage	0				2	(0.1)	2	0.10
Vaginal discharge	0				2	(0.1)	2	0.14
Colpocele	0				1	(0.1)	1	0.05
Dysmenorrhoea	0				1	(0.1)	1	0.05
Genital prolapse	0				1	(0.1)	1	0.05
Testicular cyst	0				1	(0.1)	1	0.05
Uterine enlargement	0				1	(0.1)	1	0.05
Menopausal disorder	0				1	(0.1)	1	0.09
Galactorrhoea	0				1	(0.1)	1	0.05
Penile rash	0				1	(0.1)	2	0.11
Vulvovaginal dryness	0				1	(0.1)	1	0.05
Ear and labyrinth disorders	26	(1.4)	29	1.83	22	(1.2)	23	1.61
Vertigo	10	(0.5)	11	0.73	8	(0.4)	9	0.60
Ear pain	5	(0.3)	5	0.34	1	(0.1)	1	0.09
Hypoacusis	2	(0.1)	2	0.14	3	(0.2)	3	0.16
Tinnitus	2	(0.1)	2	0.11	2	(0.1)	2	0.15
Deafness bilateral	2	(0.1)	2	0.10	0			
Vertigo positional	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Cerumen impaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Ear inflammation	1	(0.1)	1	0.05	0			
Eustachian tube dysfunction	1	(0.1)	1	0.05	1	(0.1)	1	0.09
External ear pain	1	(0.1)	1	0.05	0			
Meniere's disease	1	(0.1)	1	0.05	0			
Motion sickness	0				1	(0.1)	1	0.05
Ear discomfort	0				1	(0.1)	1	0.09
Middle ear inflammation	0				1	(0.1)	1	0.09
Presbyacusis	0				1	(0.1)	1	0.05
Deafness unilateral	0				1	(0.1)	1	0.09

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

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hepatobiliary disorders	19	(1.0)	25	1.64	21	(1.1)	25	1.71
Hepatic steatosis	8	(0.4)	8	0.47	9	(0.5)	9	0.59
Cholelithiasis	3	(0.2)	3	0.16	1	(0.1)	1	0.05
Hepatomegaly	2	(0.1)	2	0.14	0			
Alcoholic liver disease	1	(0.1)	1	0.09	0			
Gallbladder polyp	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Cholecystitis	1	(0.1)	1	0.09	0			
Hepatic function abnormal	1	(0.1)	1	0.09	2	(0.1)	2	0.15
Cholecystitis chronic	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Hyperplastic cholecystopathy	1	(0.1)	1	0.09	0			
Gallbladder cholesterolosis	1	(0.1)	1	0.05	0			
Hypertransaminasaemia	1	(0.1)	2	0.11	0			
Liver disorder	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Non-alcoholic steatohepatitis	1	(0.1)	1	0.05	0			
Hepatic mass	1	(0.1)	1	0.05	0			
Nonalcoholic fatty liver disease	0				2	(0.1)	2	0.11
Hepatic cirrhosis	0				2	(0.1)	2	0.15
Bile duct stone	0				1	(0.1)	2	0.10
Biliary dyskinesia	0				1	(0.1)	1	0.09
Hepatic cyst	0				1	(0.1)	1	0.05
Steatohepatitis	0				1	(0.1)	1	0.05
Biliary colic	0				1	(0.1)	1	0.09
Immune system disorders	12	(0.6)	13	0.88	15	(0.8)	16	1.20
Seasonal allergy	8	(0.4)	8	0.50	8	(0.4)	8	0.58
Anaphylactic reaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Drug hypersensitivity	1	(0.1)	1	0.09	0			
Hypersensitivity	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Allergy to arthropod bite	1	(0.1)	1	0.05	2	(0.1)	2	0.18
Food allergy	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Immunisation reaction	0				1	(0.1)	2	0.11
Allergy to arthropod sting	0				1	(0.1)	1	0.09
Congenital, familial and genetic disorders	6	(0.3)	6	0.47	5	(0.3)	5	0.30
Type V hyperlipidaemia	3	(0.2)	3	0.24	1	(0.1)	1	0.09
Cystic fibrosis lung	1	(0.1)	1	0.09	0			
Corneal dystrophy	1	(0.1)	1	0.09	0			
Hydrocele	1	(0.1)	1	0.05	0			
Atrial septal defect	0				1	(0.1)	1	0.05
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05
Myotonic dystrophy	0				1	(0.1)	1	0.05
Congenital syphilitic osteochondritis	0				1	(0.1)	1	0.05

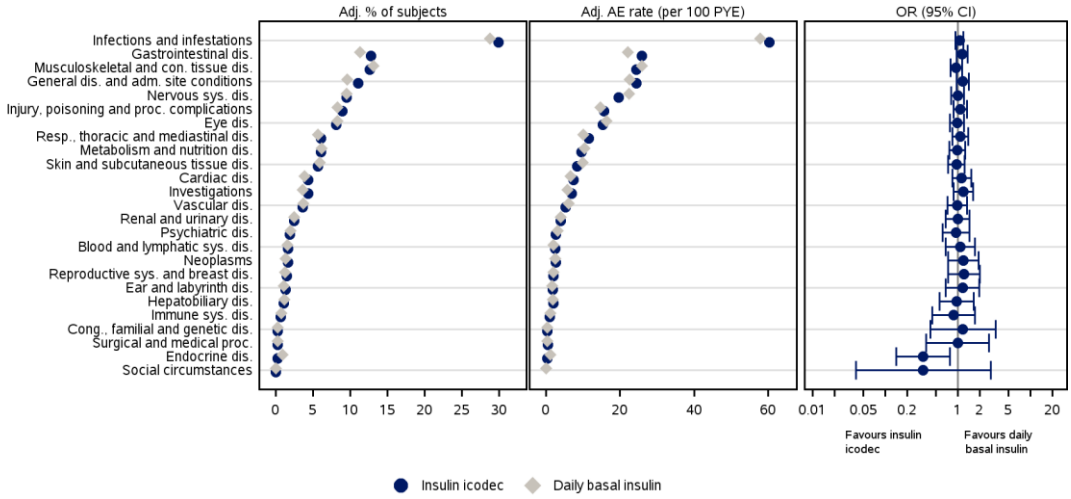
%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel 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 system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Endocrine disorders	6	(0.3)	6	0.40	18	(1.0)	18	1.18
Thyroid mass	2	(0.1)	2	0.11	2	(0.1)	2	0.14
Hypothyroidism	2	(0.1)	2	0.14	4	(0.2)	4	0.25
Hypogonadism	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Autoimmune thyroiditis	1	(0.1)	1	0.05	0			
Hyperthyroidism	0				2	(0.1)	2	0.11
Goitre	0				2	(0.1)	2	0.11
Adrenocortical insufficiency acute	0				2	(0.1)	2	0.18
Adrenal mass	0				1	(0.1)	1	0.05
Hyperplasia adrenal	0				1	(0.1)	1	0.05
Hyperprolactinaemia	0				1	(0.1)	1	0.05
Secondary hypogonadism	0				1	(0.1)	1	0.09
Inappropriate antidiuretic hormone secretion	0				1	(0.1)	1	0.09
Surgical and medical procedures	4	(0.2)	4	0.29	6	(0.3)	6	0.39
Shoulder operation	1	(0.1)	1	0.09	0			
Tooth extraction	1	(0.1)	1	0.09	0			
Knee operation	1	(0.1)	1	0.05	0			
Cardiac pacemaker replacement	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Skin neoplasm excision	0				1	(0.1)	1	0.05
Spinal operation	0				1	(0.1)	1	0.05
Large intestinal polypectomy	0				1	(0.1)	1	0.05
Removal of foreign body	0				1	(0.1)	1	0.05
Toe amputation	0				1	(0.1)	1	0.09
Social circumstances	0				1	(0.1)	1	0.09
Menopause	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.

7.2.13 Adverse events by system organ class - on-treatment/main-on-treatment - dot and forest plot - safety analysis set - phase 3a pool

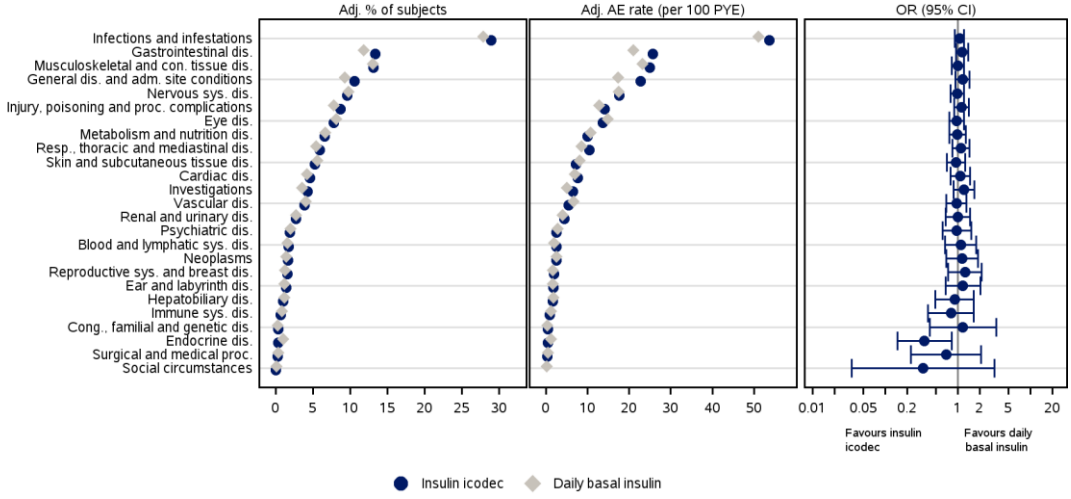


adsl.xpt; variable(s): NA; criteria: SAFFL="Y" and POOLGR2N=2
adae.axp; variable(s): AEBODSYS; criteria: SAFFL="Y" and POOLGR2N=2 and ANL06FL="Y"

% of subjects: Percentage of subjects with one or more events, AE rate: Rate (number of adverse events per 100 patient years of exposure), CI: Confidence interval, OR: Odds ratio, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. The binary endpoint of subjects having at least one event is analysed using a binary logistic regression model (logit link) applying Firth's penalised likelihood approach. The model includes treatment and trial as fixed factors. Safety analysis set. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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7.2.14 Adverse events by system organ class - on-treatment/main-on-treatment - dot and forest plot - safety analysis set - T2D pool

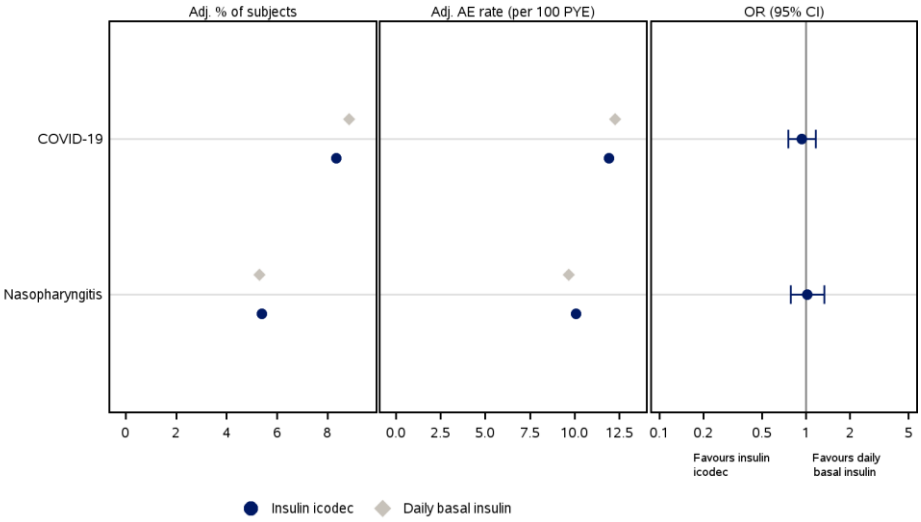


adsl.xpt; variable(s): NA; criteria: SAFFL="Y" and POOLGR1N=1
adae.axp; variable(s): AEBODSYS; criteria: SAFFL="Y" and POOLGR1N=1 and ANL06FL="Y"

% of subjects: Percentage of subjects with one or more events, AE rate: Rate (number of adverse events per 100 patient years of exposure), CI: Confidence interval, OR: Odds ratio, dis.: disorders, adm.: administration, con.: connective, proc.: procedural/procedures, sys.: system, resp.: respiratory, cong.: congenital, Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. The binary endpoint of subjects having at least one event is analysed using a binary logistic regression model (logit link) applying Firth's penalised likelihood approach. The model includes treatment and trial as fixed factors. Safety analysis set. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

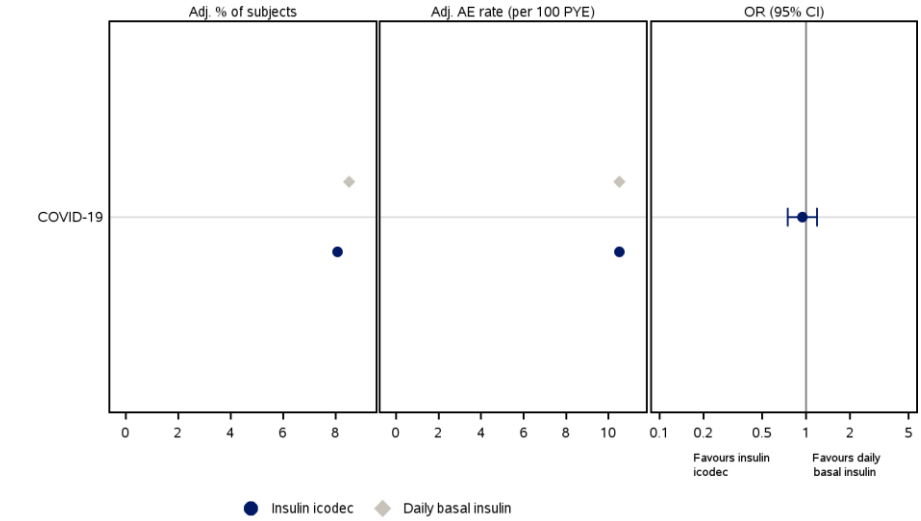


adsl.xpt; variable(s): NA; criteria: SAFFL="Y" and POOLGR2N=2
adae.axp; variable(s): AEDECOD; criteria: SAFFL="Y" and POOLGR2N=2 and ANL06FL="Y"

% of subjects: Percentage of subjects with one or more events, AE rate: Rate (number of adverse events per 100 patient years of exposure), CI: Confidence interval, OR: Odds ratio. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. The binary endpoint of subjects having at least one event is analysed using a binary logistic regression model (logit link) applying Firth's penalised likelihood approach. The model includes treatment and trial as fixed factors. Safety analysis set. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

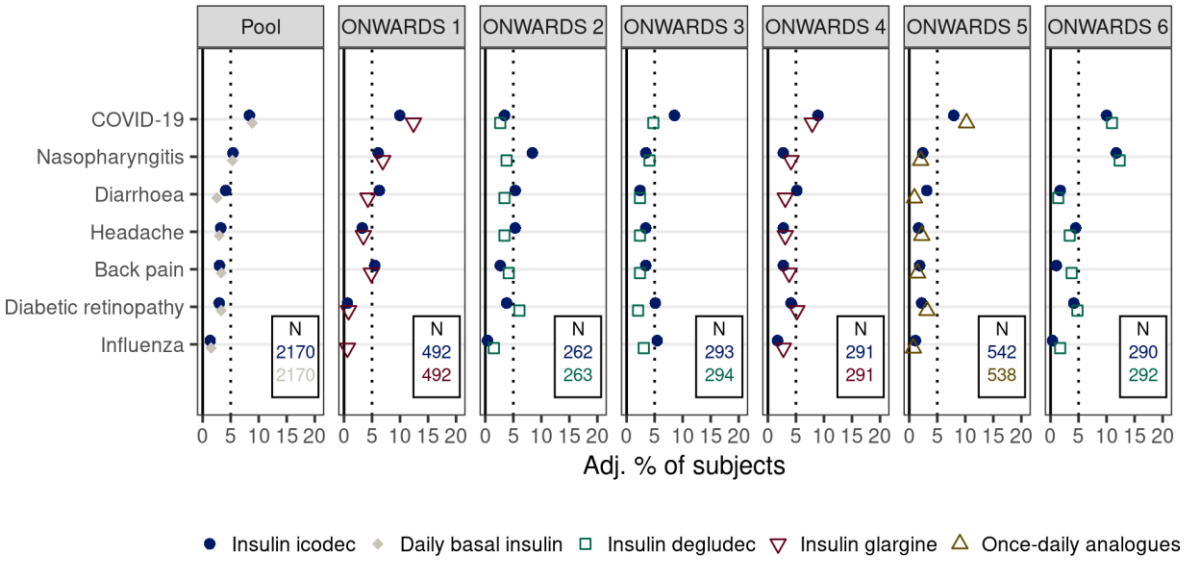


adsl.xpt; variable(s): NA; criteria: SAFFL="Y" and POOLGR1N=1
adae.axp; variable(s): AEDECOD; criteria: SAFFL="Y" and POOLGR1N=1 and ANL06FL="Y"

% of subjects: Percentage of subjects with one or more events, AE rate: Rate (number of adverse events per 100 patient years of exposure), CI: Confidence interval, OR: Odds ratio, Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. The binary endpoint of subjects having at least one event is analysed using a binary logistic regression model (logit link) applying Firth's penalised likelihood approach. The model includes treatment and trial as fixed factors. Safety analysis set. MedDRA version 24.1. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

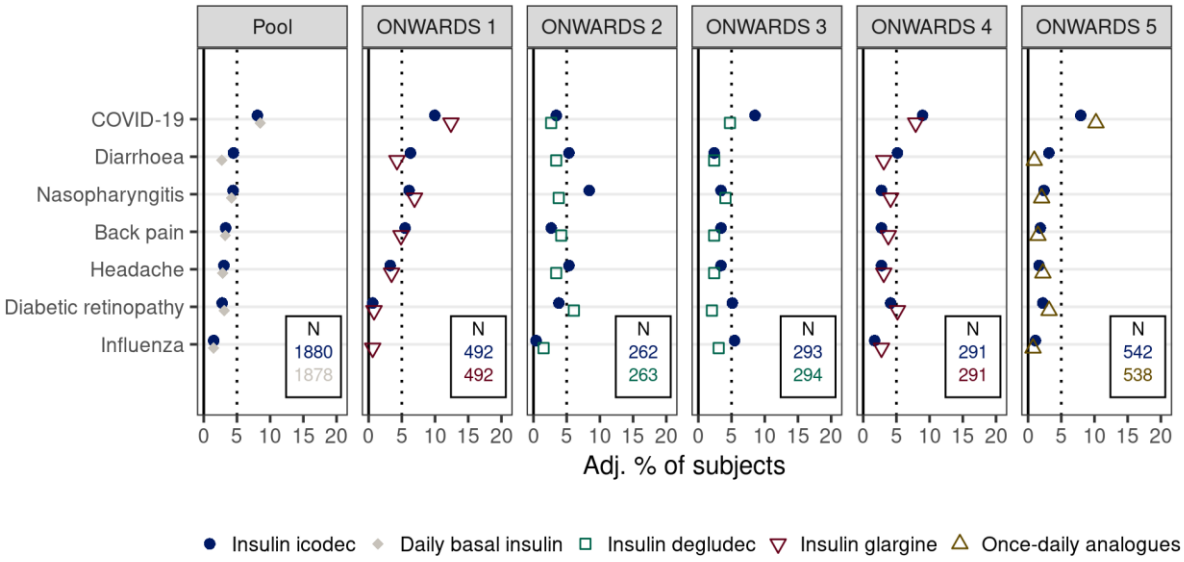


% of subjects: Percentage of subjects with one or more events, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. N: Number of subjects. Selection of preferred terms is based on the adjusted percentage of subjects with at least one event in any treatment group in any trial. Safety analysis set. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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

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7.2.18 Adverse events by preferred term and trial - 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, Adj.: Adjusted percentages were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. N: Number of subjects, Selection of preferred terms is based on the adjusted percentage of subjects with at least one event in any treatment group in any trial. Safety analysis set. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

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

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7.2.19 Adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	194	(8.9)	299	20.67	165	(7.6)	311	20.53
General disorders and administration site conditions	54	(2.5)	83	5.63	53	(2.4)	105	6.90
Injection site reaction	12	(0.6)	17	1.31	5	(0.2)	7	0.42
Hunger	7	(0.3)	8	0.45	3	(0.1)	4	0.31
Malaise	5	(0.2)	5	0.30	6	(0.3)	21	1.71
Injection site pruritus	4	(0.2)	19	1.43	1	(0.0)	1	0.08
Fatigue	3	(0.1)	3	0.17	2	(0.1)	2	0.09
Asthenia	3	(0.1)	3	0.17	4	(0.2)	4	0.29
Injection site swelling	2	(0.1)	2	0.16	0			
Injection site pain	2	(0.1)	2	0.16	10	(0.5)	28	1.47
Feeling abnormal	2	(0.1)	4	0.22	0			
Swelling face	2	(0.1)	2	0.14	0			
Oedema peripheral	2	(0.1)	2	0.12	1	(0.0)	2	0.09
Injection site urticaria	1	(0.0)	1	0.09	0			
Medical device site haematoma	1	(0.0)	1	0.09	0			
Application site bruise	1	(0.0)	1	0.08	0			
Application site pruritus	1	(0.0)	1	0.08	0			
Discomfort	1	(0.0)	1	0.08	1	(0.0)	8	0.64
Injection site bruising	1	(0.0)	1	0.08	5	(0.2)	5	0.26
Oedema	1	(0.0)	1	0.08	0			
Chest discomfort	1	(0.0)	1	0.05	0			
Chills	1	(0.0)	1	0.05	0			
Injection site erythema	1	(0.0)	1	0.05	4	(0.2)	4	0.19
Injection site hypersensitivity	1	(0.0)	1	0.05	0			
Thirst	1	(0.0)	1	0.05	0			
Chest pain	1	(0.0)	1	0.04	0			
Injection site mass	1	(0.0)	1	0.04	1	(0.0)	1	0.09
Localised oedema	1	(0.0)	1	0.04	0			
Peripheral swelling	1	(0.0)	1	0.04	0			
Injection site haematoma	0				3	(0.1)	8	0.63
Injection site induration	0				2	(0.1)	2	0.12
Injection site haemorrhage	0				2	(0.1)	2	0.13
Injection site rash	0				1	(0.0)	1	0.08
Death	0				1	(0.0)	1	0.05
Injection site hypertrophy	0				1	(0.0)	1	0.05
Swelling	0				1	(0.0)	1	0.05
Injection site oedema	0				1	(0.0)	1	0.08
Pain	0				1	(0.0)	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 possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Nervous system disorders	35	(1.6)	48	3.26	31	(1.4)	46	3.13
Dizziness	10	(0.5)	14	1.07	11	(0.5)	13	0.83
Headache	9	(0.4)	9	0.62	5	(0.2)	5	0.26
Tremor	6	(0.3)	7	0.36	7	(0.3)	14	1.19
Dysgeusia	3	(0.1)	3	0.17	0			
Neuropathy peripheral	2	(0.1)	2	0.13	0			
Disturbance in attention	1	(0.0)	3	0.28	0			
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Loss of consciousness	1	(0.0)	1	0.09	0			
Migraine	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Somnolence	1	(0.0)	1	0.08	0			
Balance disorder	1	(0.0)	1	0.05	0			
Hypoaesthesia	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Neuroglycopenia	1	(0.0)	1	0.05	1	(0.0)	3	0.14
Neuralgia	1	(0.0)	1	0.04	0			
Paraesthesia	1	(0.0)	2	0.09	1	(0.0)	1	0.08
Orthostatic tremor	0				1	(0.0)	1	0.04
Lethargy	0				1	(0.0)	1	0.05
Mental impairment	0				1	(0.0)	1	0.05
Sciatica	0				1	(0.0)	1	0.05
Syncope	0				1	(0.0)	1	0.05
Meralgia paraesthetica	0				1	(0.0)	1	0.08
Hypoglycaemic unconsciousness	0				1	(0.0)	1	0.09
Eye disorders	24	(1.1)	25	1.99	15	(0.7)	24	1.74
Diabetic retinopathy	11	(0.5)	11	0.90	6	(0.3)	6	0.39
Macular oedema	3	(0.1)	3	0.27	0			
Vision blurred	3	(0.1)	3	0.25	2	(0.1)	2	0.09
Cataract	2	(0.1)	2	0.13	0			
Retinopathy hypertensive	1	(0.0)	1	0.08	0			
Diabetic retinal oedema	1	(0.0)	1	0.08	3	(0.1)	4	0.29
Diplopia	1	(0.0)	1	0.08	0			
Retinal deposits	1	(0.0)	1	0.08	0			
Vitreous haemorrhage	1	(0.0)	1	0.08	0			
Age-related macular degeneration	1	(0.0)	1	0.04	0			
Non-proliferative retinopathy	0				2	(0.1)	2	0.17
Visual impairment	0				1	(0.0)	9	0.72
Optic disc haemorrhage	0				1	(0.0)	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 possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastrointestinal disorders	24	(1.1)	29	1.82	14	(0.6)	17	0.99
Diarrhoea	8	(0.4)	9	0.54	5	(0.2)	5	0.30
Nausea	5	(0.2)	5	0.26	3	(0.1)	3	0.14
Vomiting	2	(0.1)	2	0.16	1	(0.0)	1	0.05
Constipation	2	(0.1)	2	0.12	0			
Hypoaesthesia oral	2	(0.1)	4	0.32	0			
Dyspepsia	1	(0.0)	1	0.09	0			
Gastrooesophageal reflux disease	1	(0.0)	1	0.09	0			
Abdominal discomfort	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Dry mouth	1	(0.0)	1	0.05	0			
Abdominal distension	1	(0.0)	1	0.04	2	(0.1)	2	0.17
Abdominal pain	1	(0.0)	1	0.04	2	(0.1)	2	0.12
Lip swelling	1	(0.0)	1	0.04	0			
Gastritis	0				1	(0.0)	1	0.04
Irritable bowel syndrome	0				1	(0.0)	1	0.05
Flatulence	0				1	(0.0)	1	0.08
Metabolism and nutrition disorders	23	(1.1)	27	1.86	36	(1.7)	57	3.57
Hypoglycaemia	14	(0.6)	18	1.38	20	(0.9)	37	2.27
Increased appetite	3	(0.1)	3	0.14	4	(0.2)	5	0.36
Decreased appetite	2	(0.1)	2	0.13	1	(0.0)	1	0.04
Abnormal weight gain	1	(0.0)	1	0.08	0			
Hyperlipidaemia	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Obesity	1	(0.0)	1	0.05	1	(0.0)	1	0.09
Diabetes mellitus	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Hyperglycaemia	0				5	(0.2)	5	0.40
Gout	0				1	(0.0)	2	0.09
Insulin resistance	0				1	(0.0)	1	0.04
Appetite disorder	0				1	(0.0)	2	0.09
Food craving	0				1	(0.0)	1	0.08
Investigations	22	(1.0)	22	1.39	25	(1.2)	26	1.70
Weight increased	18	(0.8)	18	1.07	16	(0.7)	16	0.94
Alanine aminotransferase increased	2	(0.1)	2	0.16	0			
Blood glucose fluctuation	1	(0.0)	1	0.08	0			
Monocyte count decreased	1	(0.0)	1	0.08	0			
Hepatic enzyme increased	0				2	(0.1)	2	0.14
Blood urine present	0				1	(0.0)	1	0.08
Blood pressure decreased	0				1	(0.0)	1	0.05
Blood pressure increased	0				1	(0.0)	1	0.05
Blood glucose decreased	0				1	(0.0)	1	0.08
Low density lipoprotein increased	0				1	(0.0)	1	0.08
Eosinophil count increased	0				1	(0.0)	2	0.19
White blood cell count decreased	0				1	(0.0)	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. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injury, poisoning and procedural complications	21	(1.0)	22	1.82	5	(0.2)	6	0.48
Accidental overdose	8	(0.4)	9	0.72	1	(0.0)	1	0.08
Incorrect dose administered	4	(0.2)	4	0.36	1	(0.0)	2	0.16
Prescribed overdose	3	(0.1)	3	0.28	0			
Overdose	3	(0.1)	3	0.20	0			
Product administration error	1	(0.0)	1	0.09	0			
Accidental underdose	1	(0.0)	1	0.08	0			
Extra dose administered	1	(0.0)	1	0.08	0			
Wrong dose	0				2	(0.1)	2	0.16
Intentional product use issue	0				1	(0.0)	1	0.08
Skin and subcutaneous tissue disorders	18	(0.8)	18	1.11	10	(0.5)	13	0.87
Hyperhidrosis	5	(0.2)	5	0.33	2	(0.1)	2	0.16
Cold sweat	3	(0.1)	3	0.17	5	(0.2)	6	0.45
Urticaria	3	(0.1)	3	0.20	2	(0.1)	2	0.12
Rash	2	(0.1)	2	0.13	0			
Pruritus	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Rash erythematous	1	(0.0)	1	0.09	0			
Lipodystrophy acquired	1	(0.0)	1	0.05	0			
Night sweats	1	(0.0)	1	0.04	0			
Angioedema	0				1	(0.0)	1	0.04
Lipohypertrophy	0				1	(0.0)	1	0.05
Musculoskeletal and connective tissue disorders	5	(0.2)	8	0.56	6	(0.3)	6	0.42
Muscle spasms	3	(0.1)	3	0.20	0			
Soft tissue swelling	1	(0.0)	3	0.23	0			
Spinal stenosis	1	(0.0)	1	0.08	0			
Pain in extremity	1	(0.0)	1	0.05	2	(0.1)	2	0.12
Spinal osteoarthritis	0				1	(0.0)	1	0.05
Joint swelling	0				1	(0.0)	1	0.08
Muscular weakness	0				1	(0.0)	1	0.08
Rheumatoid arthritis	0				1	(0.0)	1	0.09
Psychiatric disorders	4	(0.2)	4	0.33	1	(0.0)	1	0.05
Depressed mood	1	(0.0)	1	0.09	0			
Agitation	1	(0.0)	1	0.08	0			
Drug abuse	1	(0.0)	1	0.08	0			
Irritability	1	(0.0)	1	0.08	0			
Mood swings	0				1	(0.0)	1	0.05
Infections and infestations	3	(0.1)	3	0.25	2	(0.1)	2	0.14
Rhinitis	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Otitis media	1	(0.0)	1	0.08	0			
Gastroenteritis viral	1	(0.0)	1	0.08	0			
Gastrointestinal infection	0				1	(0.0)	1	0.04
Vascular disorders	3	(0.1)	3	0.20	2	(0.1)	2	0.13
Hypertension	2	(0.1)	2	0.16	0			
Peripheral coldness	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Arteriosclerosis	0				1	(0.0)	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 possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac disorders	2	(0.1)	2	0.09	4	(0.2)	4	0.25
Palpitations	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Supraventricular extrasystoles	1	(0.0)	1	0.05	0			
Coronary artery disease	0				1	(0.0)	1	0.08
Bundle branch block right	0				1	(0.0)	1	0.05
Reproductive system and breast disorders	1	(0.0)	1	0.09	0			
Prostatomegaly	1	(0.0)	1	0.09	0			
Renal and urinary disorders	1	(0.0)	1	0.08	0			
Urine odour abnormal	1	(0.0)	1	0.08	0			
Blood and lymphatic system disorders	1	(0.0)	1	0.08	0			
Leukopenia	1	(0.0)	1	0.08	0			
Hepatobiliary disorders	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Hypertransaminasaemia	1	(0.0)	1	0.05	0			
Biliary dyskinesia	0				1	(0.0)	1	0.08
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.04	0			
Dyspnoea	1	(0.0)	1	0.04	0			
Immune system disorders	0				1	(0.0)	1	0.08
Anaphylactic reaction	0				1	(0.0)	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.

7.2.20 Adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	157	(8.4)	253	18.87	144	(7.7)	262	18.44
General disorders and administration site conditions	50	(2.7)	79	6.07	49	(2.6)	86	5.93
Injection site reaction	12	(0.6)	17	1.52	5	(0.3)	7	0.48
Hunger	6	(0.3)	7	0.41	2	(0.1)	2	0.15
Malaise	5	(0.3)	5	0.34	5	(0.3)	6	0.36
Injection site pruritus	4	(0.2)	19	1.66	1	(0.1)	1	0.09
Fatigue	3	(0.2)	3	0.20	2	(0.1)	2	0.10
Asthenia	3	(0.2)	3	0.20	4	(0.2)	4	0.33
Injection site swelling	2	(0.1)	2	0.18	0			
Injection site pain	2	(0.1)	2	0.18	9	(0.5)	27	1.59
Feeling abnormal	2	(0.1)	4	0.25	0			
Oedema peripheral	2	(0.1)	2	0.14	1	(0.1)	2	0.11
Application site bruise	1	(0.1)	1	0.09	0			
Application site pruritus	1	(0.1)	1	0.09	0			
Discomfort	1	(0.1)	1	0.09	1	(0.1)	8	0.74
Injection site bruising	1	(0.1)	1	0.09	5	(0.3)	5	0.30
Oedema	1	(0.1)	1	0.09	0			
Chest discomfort	1	(0.1)	1	0.05	0			
Chills	1	(0.1)	1	0.05	0			
Injection site erythema	1	(0.1)	1	0.05	4	(0.2)	4	0.22
Injection site hypersensitivity	1	(0.1)	1	0.05	0			
Thirst	1	(0.1)	1	0.05	0			
Chest pain	1	(0.1)	1	0.05	0			
Injection site mass	1	(0.1)	1	0.05	0			
Localised oedema	1	(0.1)	1	0.05	0			
Peripheral swelling	1	(0.1)	1	0.05	0			
Swelling face	1	(0.1)	1	0.05	0			
Injection site haematoma	0				3	(0.2)	8	0.73
Injection site induration	0				2	(0.1)	2	0.14
Injection site haemorrhage	0				2	(0.1)	2	0.15
Injection site rash	0				1	(0.1)	1	0.09
Death	0				1	(0.1)	1	0.05
Injection site hypertrophy	0				1	(0.1)	1	0.05
Swelling	0				1	(0.1)	1	0.05
Injection site oedema	0				1	(0.1)	1	0.09
Pain	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 possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/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	28	(1.5)	38	2.67	25	(1.3)	33	2.22
Dizziness	9	(0.5)	13	1.12	10	(0.5)	11	0.74
Tremor	6	(0.3)	7	0.41	5	(0.3)	6	0.51
Headache	6	(0.3)	6	0.39	5	(0.3)	5	0.30
Dysgeusia	3	(0.2)	3	0.20	0			
Neuropathy peripheral	2	(0.1)	2	0.15	0			
Somnolence	1	(0.1)	1	0.09	0			
Balance disorder	1	(0.1)	1	0.05	0			
Hypoaesthesia	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Neuroglycopenia	1	(0.1)	1	0.05	1	(0.1)	3	0.16
Neuralgia	1	(0.1)	1	0.05	0			
Paraesthesia	1	(0.1)	2	0.10	1	(0.1)	1	0.09
Orthostatic tremor	0				1	(0.1)	1	0.05
Lethargy	0				1	(0.1)	1	0.05
Mental impairment	0				1	(0.1)	1	0.05
Sciatica	0				1	(0.1)	1	0.05
Syncope	0				1	(0.1)	1	0.05
Meralgia paraesthetica	0				1	(0.1)	1	0.09
Gastrointestinal disorders	22	(1.2)	27	1.89	13	(0.7)	16	1.04
Diarrhoea	8	(0.4)	9	0.63	5	(0.3)	5	0.35
Nausea	5	(0.3)	5	0.31	3	(0.2)	3	0.16
Vomiting	2	(0.1)	2	0.18	1	(0.1)	1	0.05
Constipation	2	(0.1)	2	0.14	0			
Hypoaesthesia oral	2	(0.1)	4	0.37	0			
Abdominal discomfort	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Dry mouth	1	(0.1)	1	0.05	0			
Abdominal distension	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Abdominal pain	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Lip swelling	1	(0.1)	1	0.05	0			
Gastritis	0				1	(0.1)	1	0.05
Irritable bowel syndrome	0				1	(0.1)	1	0.05
Flatulence	0				1	(0.1)	1	0.09
Investigations	21	(1.1)	21	1.50	22	(1.2)	22	1.53
Weight increased	17	(0.9)	17	1.13	16	(0.9)	16	1.09
Alanine aminotransferase increased	2	(0.1)	2	0.18	0			
Blood glucose fluctuation	1	(0.1)	1	0.09	0			
Monocyte count decreased	1	(0.1)	1	0.09	0			
Blood urine present	0				1	(0.1)	1	0.09
Blood pressure decreased	0				1	(0.1)	1	0.05
Blood pressure increased	0				1	(0.1)	1	0.05
Hepatic enzyme increased	0				1	(0.1)	1	0.05
Blood glucose decreased	0				1	(0.1)	1	0.09
Low density lipoprotein increased	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 possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Metabolism and nutrition disorders	19	(1.0)	21	1.50	32	(1.7)	52	3.58
Hypoglycaemia	10	(0.5)	12	0.95	17	(0.9)	33	2.19
Increased appetite	3	(0.2)	3	0.16	4	(0.2)	5	0.42
Decreased appetite	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Abnormal weight gain	1	(0.1)	1	0.09	0			
Hyperlipidaemia	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Obesity	1	(0.1)	1	0.05	0			
Diabetes mellitus	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Hyperglycaemia	0				5	(0.3)	5	0.46
Gout	0				1	(0.1)	2	0.10
Insulin resistance	0				1	(0.1)	1	0.05
Appetite disorder	0				1	(0.1)	2	0.11
Food craving	0				1	(0.1)	1	0.09
Eye disorders	17	(0.9)	18	1.54	13	(0.7)	22	1.80
Diabetic retinopathy	7	(0.4)	7	0.60	5	(0.3)	5	0.34
Vision blurred	2	(0.1)	2	0.18	2	(0.1)	2	0.11
Cataract	2	(0.1)	2	0.15	0			
Retinopathy hypertensive	1	(0.1)	1	0.09	0			
Diabetic retinal oedema	1	(0.1)	1	0.09	3	(0.2)	4	0.33
Diplopia	1	(0.1)	1	0.09	0			
Macular oedema	1	(0.1)	1	0.09	0			
Retinal deposits	1	(0.1)	1	0.09	0			
Vitreous haemorrhage	1	(0.1)	1	0.09	0			
Age-related macular degeneration	1	(0.1)	1	0.05	0			
Visual impairment	0				1	(0.1)	9	0.84
Non-proliferative retinopathy	0				1	(0.1)	1	0.09
Optic disc haemorrhage	0				1	(0.1)	1	0.09
Skin and subcutaneous tissue disorders	17	(0.9)	17	1.18	8	(0.4)	10	0.68
Hyperhidrosis	5	(0.3)	5	0.38	2	(0.1)	2	0.18
Cold sweat	3	(0.2)	3	0.20	3	(0.2)	3	0.20
Urticaria	3	(0.2)	3	0.23	2	(0.1)	2	0.14
Rash	2	(0.1)	2	0.15	0			
Pruritus	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Lipodystrophy acquired	1	(0.1)	1	0.05	0			
Night sweats	1	(0.1)	1	0.05	0			
Angioedema	0				1	(0.1)	1	0.05
Lipohypertrophy	0				1	(0.1)	1	0.05
Injury, poisoning and procedural complications	10	(0.5)	10	0.80	5	(0.3)	6	0.55
Accidental overdose	4	(0.2)	4	0.29	1	(0.1)	1	0.09
Overdose	3	(0.2)	3	0.23	0			
Accidental underdose	1	(0.1)	1	0.09	0			
Extra dose administered	1	(0.1)	1	0.09	0			
Incorrect dose administered	1	(0.1)	1	0.09	1	(0.1)	2	0.19
Wrong dose	0				2	(0.1)	2	0.18
Intentional product use issue	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 possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Musculoskeletal and connective tissue disorders	5	(0.3)	8	0.65	5	(0.3)	5	0.38
Muscle spasms	3	(0.2)	3	0.24	0			
Soft tissue swelling	1	(0.1)	3	0.27	0			
Spinal stenosis	1	(0.1)	1	0.09	0			
Pain in extremity	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Spinal osteoarthritis	0				1	(0.1)	1	0.05
Joint swelling	0				1	(0.1)	1	0.09
Muscular weakness	0				1	(0.1)	1	0.09
Psychiatric disorders	3	(0.2)	3	0.27	1	(0.1)	1	0.05
Agitation	1	(0.1)	1	0.09	0			
Drug abuse	1	(0.1)	1	0.09	0			
Irritability	1	(0.1)	1	0.09	0			
Mood swings	0				1	(0.1)	1	0.05
Vascular disorders	3	(0.2)	3	0.24	2	(0.1)	2	0.15
Hypertension	2	(0.1)	2	0.18	0			
Peripheral coldness	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Arteriosclerosis	0				1	(0.1)	1	0.09
Infections and infestations	2	(0.1)	2	0.18	1	(0.1)	1	0.05
Otitis media	1	(0.1)	1	0.09	0			
Gastroenteritis viral	1	(0.1)	1	0.09	0			
Gastrointestinal infection	0				1	(0.1)	1	0.05
Cardiac disorders	2	(0.1)	2	0.11	4	(0.2)	4	0.29
Palpitations	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Supraventricular extrasystoles	1	(0.1)	1	0.05	0			
Coronary artery disease	0				1	(0.1)	1	0.09
Bundle branch block right	0				1	(0.1)	1	0.05
Renal and urinary disorders	1	(0.1)	1	0.09	0			
Urine odour abnormal	1	(0.1)	1	0.09	0			
Blood and lymphatic system disorders	1	(0.1)	1	0.09	0			
Leukopenia	1	(0.1)	1	0.09	0			
Hepatobiliary disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Hypertransaminasaemia	1	(0.1)	1	0.05	0			
Biliary dyskinesia	0				1	(0.1)	1	0.09
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.05	0			
Dyspnoea	1	(0.1)	1	0.05	0			
Immune system disorders	0				1	(0.1)	1	0.09
Anaphylactic reaction	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.

7.2.21 Severe adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	92	(4.2)	121	7.70	89	(4.1)	133	7.32
Infections and infestations	31	(1.4)	34	2.26	19	(0.9)	21	1.05
COVID-19	9	(0.4)	9	0.61	2	(0.1)	2	0.09
COVID-19 pneumonia	4	(0.2)	4	0.28	4	(0.2)	4	0.18
Pneumonia	4	(0.2)	4	0.28	0			
Sepsis	2	(0.1)	2	0.16	1	(0.0)	1	0.05
Influenza	2	(0.1)	2	0.12	0			
Bronchitis	2	(0.1)	2	0.09	0			
Abscess limb	1	(0.0)	1	0.08	0			
Paraspinal abscess	1	(0.0)	1	0.08	0			
Cystitis	1	(0.0)	1	0.08	0			
Bacteraemia	1	(0.0)	1	0.08	0			
Cholecystitis infective	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Diabetic foot infection	1	(0.0)	1	0.08	0			
Cellulitis	1	(0.0)	1	0.05	2	(0.1)	2	0.09
Osteomyelitis	1	(0.0)	1	0.05	0			
Upper respiratory tract infection	1	(0.0)	1	0.05	0			
Appendicitis	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Gangrene	1	(0.0)	1	0.04	0			
Abdominal abscess	0				1	(0.0)	1	0.04
Abscess	0				1	(0.0)	1	0.04
Urosepsis	0				1	(0.0)	1	0.04
Viral infection	0				1	(0.0)	1	0.04
Clostridium difficile infection	0				1	(0.0)	1	0.05
Empyema	0				1	(0.0)	1	0.05
Post procedural infection	0				1	(0.0)	1	0.05
Erysipelas	0				1	(0.0)	1	0.08
Herpes zoster	0				1	(0.0)	1	0.08
Soft tissue infection	0				1	(0.0)	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.

Severe adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac disorders	20	(0.9)	22	1.20	18	(0.8)	26	1.48
Acute myocardial infarction	4	(0.2)	4	0.18	7	(0.3)	7	0.42
Myocardial infarction	3	(0.1)	3	0.20	3	(0.1)	3	0.14
Cardiac failure	3	(0.1)	3	0.14	0			
Acute coronary syndrome	2	(0.1)	2	0.09	0			
Cardiac failure congestive	2	(0.1)	2	0.09	2	(0.1)	3	0.24
Coronary artery disease	2	(0.1)	2	0.09	3	(0.1)	3	0.14
Supraventricular tachycardia	1	(0.0)	1	0.08	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Angina pectoris	1	(0.0)	1	0.08	0			
Myocardial ischaemia	1	(0.0)	1	0.08	1	(0.0)	1	0.09
Angina unstable	1	(0.0)	1	0.05	1	(0.0)	1	0.09
Atrial fibrillation	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Cardiac arrest	0				2	(0.1)	2	0.09
Cardiac failure acute	0				1	(0.0)	1	0.04
Palpitations	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrioventricular block complete	0				1	(0.0)	1	0.05
Left ventricular dysfunction	0				1	(0.0)	1	0.05
Injury, poisoning and procedural complications	12	(0.6)	16	1.06	7	(0.3)	8	0.43
Road traffic accident	2	(0.1)	2	0.12	1	(0.0)	1	0.04
Fall	2	(0.1)	2	0.12	1	(0.0)	1	0.04
Hip fracture	2	(0.1)	2	0.09	0			
Procedural pain	1	(0.0)	1	0.09	0			
Product administration error	1	(0.0)	1	0.09	0			
Skin abrasion	1	(0.0)	1	0.08	0			
Wrist fracture	1	(0.0)	1	0.08	0			
Gun shot wound	1	(0.0)	1	0.08	0			
Procedural complication	1	(0.0)	1	0.08	0			
Subdural haematoma	1	(0.0)	1	0.08	0			
Post procedural haemorrhage	1	(0.0)	1	0.05	0			
Femoral neck fracture	1	(0.0)	1	0.04	0			
Post procedural haematuria	1	(0.0)	1	0.04	0			
Rib fracture	0				2	(0.1)	2	0.09
Ankle fracture	0				1	(0.0)	1	0.04
Meniscus injury	0				1	(0.0)	1	0.08
Spinal compression fracture	0				1	(0.0)	1	0.08
Radius fracture	0				1	(0.0)	1	0.05
Metabolism and nutrition disorders	7	(0.3)	8	0.63	3	(0.1)	3	0.17
Hypoglycaemia	5	(0.2)	6	0.54	0			
Hyperkalaemia	1	(0.0)	1	0.05	0			
Malnutrition	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Gout	0				1	(0.0)	1	0.04
Hyperglycaemia	0				1	(0.0)	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.

Severe adverse events by system organ class and preferred term - on-treatment/main-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)	6	(0.3)	7	0.35	12	(0.6)	16	0.86
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Pancreatic neoplasm	1	(0.0)	1	0.05	0			
Adenocarcinoma pancreas	1	(0.0)	1	0.04	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Colorectal cancer	1	(0.0)	1	0.04	0			
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Basal cell carcinoma	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Lung cancer metastatic	0				1	(0.0)	1	0.04
Malignant peritoneal neoplasm	0				1	(0.0)	1	0.04
Metastases to bone marrow	0				1	(0.0)	1	0.04
Pancreatic carcinoma	0				1	(0.0)	1	0.04
Uterine leiomyoma	0				1	(0.0)	1	0.04
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Nervous system disorders	5	(0.2)	5	0.41	13	(0.6)	15	0.91
Transient ischaemic attack	2	(0.1)	2	0.13	0			
Haemorrhage intracranial	1	(0.0)	1	0.09	0			
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Loss of consciousness	1	(0.0)	1	0.09	1	(0.0)	1	0.04
Burning sensation	0				1	(0.0)	1	0.04
Carpal tunnel syndrome	0				1	(0.0)	1	0.04
Cerebral artery embolism	0				1	(0.0)	1	0.04
Lumbar radiculopathy	0				1	(0.0)	2	0.09
Radiculopathy	0				1	(0.0)	1	0.04
White matter lesion	0				1	(0.0)	1	0.04
Cerebrovascular accident	0				1	(0.0)	1	0.08
Hypoglycaemic coma	0				1	(0.0)	1	0.08
Carotid arteriosclerosis	0				1	(0.0)	1	0.05
Headache	0				1	(0.0)	1	0.08
Thrombotic stroke	0				1	(0.0)	1	0.08
Hypoglycaemic unconsciousness	0				1	(0.0)	1	0.09
Renal and urinary disorders	4	(0.2)	5	0.40	6	(0.3)	6	0.31
Urethral stenosis	1	(0.0)	1	0.08	0			
Renal failure	1	(0.0)	1	0.08	0			
Ureterolithiasis	1	(0.0)	1	0.08	0			
Acute kidney injury	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Chronic kidney disease	1	(0.0)	1	0.08	2	(0.1)	2	0.12
Bladder mass	0				1	(0.0)	1	0.04
Stress urinary incontinence	0				1	(0.0)	1	0.04
Urinary tract obstruction	0				1	(0.0)	1	0.05

%: 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.

Severe adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Musculoskeletal and connective tissue disorders	3	(0.1)	3	0.17	7	(0.3)	7	0.40
Intervertebral disc protrusion	1	(0.0)	1	0.08	0			
Back pain	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Osteoarthritis	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Arthralgia	0				4	(0.2)	4	0.23
Arthritis	0				1	(0.0)	1	0.08
Blood and lymphatic system disorders	3	(0.1)	3	0.17	2	(0.1)	2	0.09
Anaemia	3	(0.1)	3	0.17	0			
Pancytopenia	0				1	(0.0)	1	0.04
Blood loss anaemia	0				1	(0.0)	1	0.05
Skin and subcutaneous tissue disorders	3	(0.1)	3	0.20	1	(0.0)	1	0.04
Urticaria	2	(0.1)	2	0.12	0			
Skin ulcer	1	(0.0)	1	0.08	0			
Pruritus	0				1	(0.0)	1	0.04
Vascular disorders	3	(0.1)	3	0.14	1	(0.0)	1	0.04
Hypertensive urgency	1	(0.0)	1	0.05	0			
Peripheral arterial occlusive disease	1	(0.0)	1	0.05	0			
Arteriosclerosis	1	(0.0)	1	0.04	0			
Aortic aneurysm	0				1	(0.0)	1	0.04
Respiratory, thoracic and mediastinal disorders	2	(0.1)	2	0.12	4	(0.2)	6	0.27
Acute respiratory failure	2	(0.1)	2	0.12	1	(0.0)	1	0.05
Pleural effusion	0				2	(0.1)	2	0.09
Dyspnoea exertional	0				1	(0.0)	1	0.04
Respiratory failure	0				1	(0.0)	1	0.04
Acute pulmonary oedema	0				1	(0.0)	1	0.05
Investigations	2	(0.1)	2	0.12	0			
Blood glucose fluctuation	1	(0.0)	1	0.08	0			
Hepatic enzyme increased	1	(0.0)	1	0.04	0			
Psychiatric disorders	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Mental status changes	1	(0.0)	1	0.08	0			
Stress	1	(0.0)	1	0.04	0			
Depression	0				1	(0.0)	1	0.08
Immune system disorders	1	(0.0)	1	0.09	1	(0.0)	1	0.08
Hypersensitivity	1	(0.0)	1	0.09	0			
Anaphylactic reaction	0				1	(0.0)	1	0.08
General disorders and administration site conditions	1	(0.0)	1	0.08	4	(0.2)	5	0.22
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Death	0				3	(0.1)	3	0.14
Pain	0				1	(0.0)	1	0.04
Systemic inflammatory response syndrome	0				1	(0.0)	1	0.04

%: 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.

Severe adverse events by system organ class and preferred term - on-treatment/main-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 and labyrinth disorders	1	(0.0)	1	0.04	0			
Vertigo positional	1	(0.0)	1	0.04	0			
Eye disorders	1	(0.0)	1	0.04	5	(0.2)	5	0.26
Visual impairment	1	(0.0)	1	0.04	0			
Cataract	0				3	(0.1)	3	0.14
Diabetic retinopathy	0				2	(0.1)	2	0.12
Gastrointestinal disorders	1	(0.0)	1	0.04	7	(0.3)	7	0.49
Diarrhoea	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Abdominal pain	0				1	(0.0)	1	0.04
Gastrointestinal haemorrhage	0				1	(0.0)	1	0.08
Upper gastrointestinal haemorrhage	0				1	(0.0)	1	0.08
Pancreatitis acute	0				1	(0.0)	1	0.05
Abdominal pain upper	0				1	(0.0)	1	0.08
Gastric dysplasia	0				1	(0.0)	1	0.08
Hepatobiliary disorders	1	(0.0)	1	0.04	0			
Cholelithiasis	1	(0.0)	1	0.04	0			
Congenital, familial and genetic disorders	0				1	(0.0)	1	0.04
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Surgical and medical procedures	0				1	(0.0)	1	0.08
Toe amputation	0				1	(0.0)	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.

7.2.22 Severe adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	83	(4.4)	111	7.81	85	(4.5)	128	7.92
Infections and infestations	31	(1.6)	34	2.61	19	(1.0)	21	1.22
COVID-19	9	(0.5)	9	0.70	2	(0.1)	2	0.11
COVID-19 pneumonia	4	(0.2)	4	0.33	4	(0.2)	4	0.21
Pneumonia	4	(0.2)	4	0.33	0			
Sepsis	2	(0.1)	2	0.18	1	(0.1)	1	0.05
Influenza	2	(0.1)	2	0.14	0			
Bronchitis	2	(0.1)	2	0.11	0			
Abscess limb	1	(0.1)	1	0.09	0			
Paraspinal abscess	1	(0.1)	1	0.09	0			
Cystitis	1	(0.1)	1	0.09	0			
Bacteraemia	1	(0.1)	1	0.09	0			
Cholecystitis infective	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Diabetic foot infection	1	(0.1)	1	0.09	0			
Cellulitis	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Osteomyelitis	1	(0.1)	1	0.05	0			
Upper respiratory tract infection	1	(0.1)	1	0.05	0			
Appendicitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Gangrene	1	(0.1)	1	0.05	0			
Abdominal abscess	0				1	(0.1)	1	0.05
Abscess	0				1	(0.1)	1	0.05
Urosepsis	0				1	(0.1)	1	0.05
Viral infection	0				1	(0.1)	1	0.05
Clostridium difficile infection	0				1	(0.1)	1	0.05
Empyema	0				1	(0.1)	1	0.05
Post procedural infection	0				1	(0.1)	1	0.05
Erysipelas	0				1	(0.1)	1	0.09
Herpes zoster	0				1	(0.1)	1	0.09
Soft tissue infection	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.

Severe adverse events by system organ class and preferred term - on-treatment/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	20	(1.1)	22	1.39	17	(0.9)	24	1.50
Acute myocardial infarction	4	(0.2)	4	0.21	7	(0.4)	7	0.49
Myocardial infarction	3	(0.2)	3	0.24	3	(0.2)	3	0.16
Cardiac failure	3	(0.2)	3	0.16	0			
Acute coronary syndrome	2	(0.1)	2	0.11	0			
Cardiac failure congestive	2	(0.1)	2	0.11	2	(0.1)	3	0.28
Coronary artery disease	2	(0.1)	2	0.11	3	(0.2)	3	0.16
Supraventricular tachycardia	1	(0.1)	1	0.09	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Angina pectoris	1	(0.1)	1	0.09	0			
Myocardial ischaemia	1	(0.1)	1	0.09	0			
Angina unstable	1	(0.1)	1	0.05	0			
Atrial fibrillation	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Cardiac arrest	0				2	(0.1)	2	0.10
Cardiac failure acute	0				1	(0.1)	1	0.05
Palpitations	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrioventricular block complete	0				1	(0.1)	1	0.05
Left ventricular dysfunction	0				1	(0.1)	1	0.05
Injury, poisoning and procedural complications	10	(0.5)	14	1.00	7	(0.4)	8	0.50
Road traffic accident	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Fall	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Hip fracture	2	(0.1)	2	0.11	0			
Skin abrasion	1	(0.1)	1	0.09	0			
Wrist fracture	1	(0.1)	1	0.09	0			
Gun shot wound	1	(0.1)	1	0.09	0			
Procedural complication	1	(0.1)	1	0.09	0			
Subdural haematoma	1	(0.1)	1	0.09	0			
Post procedural haemorrhage	1	(0.1)	1	0.05	0			
Femoral neck fracture	1	(0.1)	1	0.05	0			
Post procedural haematuria	1	(0.1)	1	0.05	0			
Rib fracture	0				2	(0.1)	2	0.11
Ankle fracture	0				1	(0.1)	1	0.05
Meniscus injury	0				1	(0.1)	1	0.09
Spinal compression fracture	0				1	(0.1)	1	0.09
Radius fracture	0				1	(0.1)	1	0.05

%: 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.

Severe adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D 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)	6	(0.3)	7	0.40	12	(0.6)	16	0.99
Metastases to liver	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Pancreatic neoplasm	1	(0.1)	1	0.05	0			
Adenocarcinoma pancreas	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Colorectal cancer	1	(0.1)	1	0.05	0			
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Basal cell carcinoma	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Lung cancer metastatic	0				1	(0.1)	1	0.05
Malignant peritoneal neoplasm	0				1	(0.1)	1	0.05
Metastases to bone marrow	0				1	(0.1)	1	0.05
Pancreatic carcinoma	0				1	(0.1)	1	0.05
Uterine leiomyoma	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Renal and urinary disorders	4	(0.2)	5	0.46	6	(0.3)	6	0.35
Urethral stenosis	1	(0.1)	1	0.09	0			
Renal failure	1	(0.1)	1	0.09	0			
Ureterolithiasis	1	(0.1)	1	0.09	0			
Acute kidney injury	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Chronic kidney disease	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Bladder mass	0				1	(0.1)	1	0.05
Stress urinary incontinence	0				1	(0.1)	1	0.05
Urinary tract obstruction	0				1	(0.1)	1	0.05
Metabolism and nutrition disorders	4	(0.2)	4	0.29	3	(0.2)	3	0.20
Hypoglycaemia	2	(0.1)	2	0.19	0			
Hyperkalaemia	1	(0.1)	1	0.05	0			
Malnutrition	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Gout	0				1	(0.1)	1	0.05
Hyperglycaemia	0				1	(0.1)	1	0.09
Musculoskeletal and connective tissue disorders	3	(0.2)	3	0.20	6	(0.3)	6	0.35
Intervertebral disc protrusion	1	(0.1)	1	0.09	0			
Back pain	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Osteoarthritis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Arthralgia	0				3	(0.2)	3	0.16
Arthritis	0				1	(0.1)	1	0.09
Skin and subcutaneous tissue disorders	3	(0.2)	3	0.23	1	(0.1)	1	0.05
Urticaria	2	(0.1)	2	0.14	0			
Skin ulcer	1	(0.1)	1	0.09	0			
Pruritus	0				1	(0.1)	1	0.05

%: 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.

Severe adverse events by system organ class and preferred term - on-treatment/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 and lymphatic system disorders	3	(0.2)	3	0.20	2	(0.1)	2	0.11
Anaemia	3	(0.2)	3	0.20	0			
Pancytopenia	0				1	(0.1)	1	0.05
Blood loss anaemia	0				1	(0.1)	1	0.05
Vascular disorders	3	(0.2)	3	0.16	1	(0.1)	1	0.05
Hypertensive urgency	1	(0.1)	1	0.05	0			
Peripheral arterial occlusive disease	1	(0.1)	1	0.05	0			
Arteriosclerosis	1	(0.1)	1	0.05	0			
Aortic aneurysm	0				1	(0.1)	1	0.05
Nervous system disorders	2	(0.1)	2	0.15	11	(0.6)	13	0.83
Transient ischaemic attack	2	(0.1)	2	0.15	0			
Burning sensation	0				1	(0.1)	1	0.05
Carpal tunnel syndrome	0				1	(0.1)	1	0.05
Cerebral artery embolism	0				1	(0.1)	1	0.05
Loss of consciousness	0				1	(0.1)	1	0.05
Lumbar radiculopathy	0				1	(0.1)	2	0.10
Radiculopathy	0				1	(0.1)	1	0.05
White matter lesion	0				1	(0.1)	1	0.05
Cerebrovascular accident	0				1	(0.1)	1	0.09
Hypoglycaemic coma	0				1	(0.1)	1	0.09
Carotid arteriosclerosis	0				1	(0.1)	1	0.05
Headache	0				1	(0.1)	1	0.09
Thrombotic stroke	0				1	(0.1)	1	0.09
Respiratory, thoracic and mediastinal disorders	2	(0.1)	2	0.14	4	(0.2)	6	0.32
Acute respiratory failure	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Pleural effusion	0				2	(0.1)	2	0.11
Dyspnoea exertional	0				1	(0.1)	1	0.05
Respiratory failure	0				1	(0.1)	1	0.05
Acute pulmonary oedema	0				1	(0.1)	1	0.05
Investigations	2	(0.1)	2	0.14	0			
Blood glucose fluctuation	1	(0.1)	1	0.09	0			
Hepatic enzyme increased	1	(0.1)	1	0.05	0			
Psychiatric disorders	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Mental status changes	1	(0.1)	1	0.09	0			
Stress	1	(0.1)	1	0.05	0			
Depression	0				1	(0.1)	1	0.09
General disorders and administration site conditions	1	(0.1)	1	0.09	4	(0.2)	5	0.26
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Death	0				3	(0.2)	3	0.16
Pain	0				1	(0.1)	1	0.05
Systemic inflammatory response syndrome	0				1	(0.1)	1	0.05
Ear and labyrinth disorders	1	(0.1)	1	0.05	0			
Vertigo positional	1	(0.1)	1	0.05	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.

Severe adverse events by system organ class and preferred term - on-treatment/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 disorders	1	(0.1)	1	0.05	5	(0.3)	5	0.30
Visual impairment	1	(0.1)	1	0.05	0			
Cataract	0				3	(0.2)	3	0.16
Diabetic retinopathy	0				2	(0.1)	2	0.14
Gastrointestinal disorders	1	(0.1)	1	0.05	7	(0.4)	7	0.57
Diarrhoea	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Abdominal pain	0				1	(0.1)	1	0.05
Gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Upper gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Pancreatitis acute	0				1	(0.1)	1	0.05
Abdominal pain upper	0				1	(0.1)	1	0.09
Gastric dysplasia	0				1	(0.1)	1	0.09
Hepatobiliary disorders	1	(0.1)	1	0.05	0			
Cholelithiasis	1	(0.1)	1	0.05	0			
Congenital, familial and genetic disorders	0				1	(0.1)	1	0.05
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05
Immune system disorders	0				1	(0.1)	1	0.09
Anaphylactic reaction	0				1	(0.1)	1	0.09
Surgical and medical procedures	0				1	(0.1)	1	0.09
Toe amputation	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.

7.2.23 Severe adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	10	(0.5)	11	0.94	7	(0.3)	7	0.52
Metabolism and nutrition disorders	4	(0.2)	5	0.46	1	(0.0)	1	0.08
Hypoglycaemia	4	(0.2)	5	0.46	0			
Hyperglycaemia	0				1	(0.0)	1	0.08
Nervous system disorders	2	(0.1)	2	0.19	2	(0.1)	2	0.19
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Loss of consciousness	1	(0.0)	1	0.09	0			
Hypoglycaemic unconsciousness	0				1	(0.0)	1	0.09
Skin and subcutaneous tissue disorders	2	(0.1)	2	0.12	1	(0.0)	1	0.04
Urticaria	2	(0.1)	2	0.12	0			
Pruritus	0				1	(0.0)	1	0.04
Injury, poisoning and procedural complications	1	(0.0)	1	0.09	0			
Product administration error	1	(0.0)	1	0.09	0			
Investigations	1	(0.0)	1	0.08	0			
Blood glucose fluctuation	1	(0.0)	1	0.08	0			
General disorders and administration site conditions	0				1	(0.0)	1	0.05
Death	0				1	(0.0)	1	0.05
Gastrointestinal disorders	0				1	(0.0)	1	0.08
Diarrhoea	0				1	(0.0)	1	0.08
Immune system disorders	0				1	(0.0)	1	0.08
Anaphylactic reaction	0				1	(0.0)	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.

7.2.24 Severe adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	4	(0.2)	4	0.33	5	(0.3)	5	0.38
Skin and subcutaneous tissue disorders	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Urticaria	2	(0.1)	2	0.14	0			
Pruritus	0				1	(0.1)	1	0.05
Investigations	1	(0.1)	1	0.09	0			
Blood glucose fluctuation	1	(0.1)	1	0.09	0			
Metabolism and nutrition disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Hypoglycaemia	1	(0.1)	1	0.09	0			
Hyperglycaemia	0				1	(0.1)	1	0.09
General disorders and administration site conditions	0				1	(0.1)	1	0.05
Death	0				1	(0.1)	1	0.05
Gastrointestinal disorders	0				1	(0.1)	1	0.09
Diarrhoea	0				1	(0.1)	1	0.09
Immune system disorders	0				1	(0.1)	1	0.09
Anaphylactic reaction	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.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & ASEV == "SEVERE" & AREL1 %in% c("POSSIBLE", "PROBABLE") & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:51 - taesocpt/taesocptsevrelsumontt2dsas.txt

7.2.25 Adverse events in subjects co-participating in a COVID-19 trial - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & C19TFL == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:06:20 - taesum/taecov19sumontp3asas.txt

7.2.26 Adverse events in subjects co-participating in a COVID-19 trial - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & C19TFL == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:06:22 - taesum/taecov19sumontt2dsas.txt

7.2.27 Adverse events by system organ class and preferred term in subjects co-participating in a COVID-19 trial - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & C19TFL == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:53 - taesocpt/taesocptcov19sumontp3asas.txt

7.2.28 Adverse events by system organ class and preferred term in subjects co-participating in a COVID-19 trial - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & C19TFL == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
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7.2.29 Adverse events with fatal outcome by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	14	(0.6)	18	1.17	13	(0.6)	15	0.81
Infections and infestations	5	(0.2)	5	0.36	3	(0.1)	3	0.14
COVID-19	3	(0.1)	3	0.20	0			
Sepsis	1	(0.0)	1	0.08	0			
COVID-19 pneumonia	1	(0.0)	1	0.08	2	(0.1)	2	0.09
Post procedural infection	0				1	(0.0)	1	0.05
Cardiac disorders	3	(0.1)	3	0.17	4	(0.2)	4	0.21
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Acute coronary syndrome	1	(0.0)	1	0.05	0			
Cardiac failure	1	(0.0)	1	0.04	0			
Cardiac arrest	0				1	(0.0)	1	0.04
Myocardial infarction	0				1	(0.0)	1	0.04
Angina pectoris	0				1	(0.0)	1	0.05
Acute myocardial infarction	0				1	(0.0)	1	0.08
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	(0.1)	4	0.18	2	(0.1)	2	0.12
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Metastases to liver	1	(0.0)	1	0.05	0			
Pancreatic neoplasm	1	(0.0)	1	0.05	0			
Adenocarcinoma pancreas	1	(0.0)	1	0.04	0			
Breast cancer metastatic	0				1	(0.0)	1	0.04
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Nervous system disorders	1	(0.0)	1	0.09	1	(0.0)	1	0.08
Haemorrhage intracranial	1	(0.0)	1	0.09	0			
Thrombotic stroke	0				1	(0.0)	1	0.08
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Acute respiratory failure	1	(0.0)	1	0.08	0			
Respiratory failure	0				1	(0.0)	1	0.04
General disorders and administration site conditions	1	(0.0)	1	0.08	3	(0.1)	3	0.14
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Death	0				3	(0.1)	3	0.14
Renal and urinary disorders	1	(0.0)	2	0.16	0			
Acute kidney injury	1	(0.0)	1	0.08	0			
Chronic kidney disease	1	(0.0)	1	0.08	0			
Vascular disorders	1	(0.0)	1	0.04	0			
Arteriosclerosis	1	(0.0)	1	0.04	0			
Gastrointestinal disorders	0				1	(0.0)	1	0.08
Gastrointestinal haemorrhage	0				1	(0.0)	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.

7.2.30 Adverse events with fatal outcome by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	13	(0.7)	17	1.25	13	(0.7)	15	0.94
Infections and infestations	5	(0.3)	5	0.42	3	(0.2)	3	0.16
COVID-19	3	(0.2)	3	0.23	0			
Sepsis	1	(0.1)	1	0.09	0			
COVID-19 pneumonia	1	(0.1)	1	0.09	2	(0.1)	2	0.10
Post procedural infection	0				1	(0.1)	1	0.05
Cardiac disorders	3	(0.2)	3	0.20	4	(0.2)	4	0.25
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Acute coronary syndrome	1	(0.1)	1	0.05	0			
Cardiac failure	1	(0.1)	1	0.05	0			
Cardiac arrest	0				1	(0.1)	1	0.05
Myocardial infarction	0				1	(0.1)	1	0.05
Angina pectoris	0				1	(0.1)	1	0.05
Acute myocardial infarction	0				1	(0.1)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	(0.2)	4	0.21	2	(0.1)	2	0.14
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Metastases to liver	1	(0.1)	1	0.05	0			
Pancreatic neoplasm	1	(0.1)	1	0.05	0			
Adenocarcinoma pancreas	1	(0.1)	1	0.05	0			
Breast cancer metastatic	0				1	(0.1)	1	0.05
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Acute respiratory failure	1	(0.1)	1	0.09	0			
Respiratory failure	0				1	(0.1)	1	0.05
General disorders and administration site conditions	1	(0.1)	1	0.09	3	(0.2)	3	0.16
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Death	0				3	(0.2)	3	0.16
Renal and urinary disorders	1	(0.1)	2	0.19	0			
Acute kidney injury	1	(0.1)	1	0.09	0			
Chronic kidney disease	1	(0.1)	1	0.09	0			
Vascular disorders	1	(0.1)	1	0.05	0			
Arteriosclerosis	1	(0.1)	1	0.05	0			
Gastrointestinal disorders	0				1	(0.1)	1	0.09
Gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Nervous system disorders	0				1	(0.1)	1	0.09
Thrombotic stroke	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.

7.2.31 Adverse events with fatal outcome by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	14	(0.6)	18	1.16	13	(0.6)	15	0.80
Infections and infestations	5	(0.2)	5	0.36	3	(0.1)	3	0.13
COVID-19	3	(0.1)	3	0.20	0			
Sepsis	1	(0.0)	1	0.08	0			
COVID-19 pneumonia	1	(0.0)	1	0.08	2	(0.1)	2	0.09
Post procedural infection	0				1	(0.0)	1	0.05
Cardiac disorders	3	(0.1)	3	0.17	4	(0.2)	4	0.21
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Acute coronary syndrome	1	(0.0)	1	0.05	0			
Cardiac failure	1	(0.0)	1	0.04	0			
Cardiac arrest	0				1	(0.0)	1	0.04
Myocardial infarction	0				1	(0.0)	1	0.04
Angina pectoris	0				1	(0.0)	1	0.05
Acute myocardial infarction	0				1	(0.0)	1	0.08
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	(0.1)	4	0.18	2	(0.1)	2	0.12
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Metastases to liver	1	(0.0)	1	0.05	0			
Pancreatic neoplasm	1	(0.0)	1	0.05	0			
Adenocarcinoma pancreas	1	(0.0)	1	0.04	0			
Breast cancer metastatic	0				1	(0.0)	1	0.04
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Nervous system disorders	1	(0.0)	1	0.09	1	(0.0)	1	0.08
Haemorrhage intracranial	1	(0.0)	1	0.09	0			
Thrombotic stroke	0				1	(0.0)	1	0.08
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Acute respiratory failure	1	(0.0)	1	0.08	0			
Respiratory failure	0				1	(0.0)	1	0.04
General disorders and administration site conditions	1	(0.0)	1	0.08	3	(0.1)	3	0.13
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Death	0				3	(0.1)	3	0.13
Renal and urinary disorders	1	(0.0)	2	0.16	0			
Acute kidney injury	1	(0.0)	1	0.08	0			
Chronic kidney disease	1	(0.0)	1	0.08	0			
Vascular disorders	1	(0.0)	1	0.04	0			
Arteriosclerosis	1	(0.0)	1	0.04	0			
Gastrointestinal disorders	0				1	(0.0)	1	0.08
Gastrointestinal haemorrhage	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.2.32 Adverse events with fatal outcome by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	13	(0.7)	17	1.23	13	(0.7)	15	0.92
Infections and infestations	5	(0.3)	5	0.41	3	(0.2)	3	0.15
COVID-19	3	(0.2)	3	0.23	0			
Sepsis	1	(0.1)	1	0.09	0			
COVID-19 pneumonia	1	(0.1)	1	0.09	2	(0.1)	2	0.10
Post procedural infection	0				1	(0.1)	1	0.05
Cardiac disorders	3	(0.2)	3	0.19	4	(0.2)	4	0.24
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Acute coronary syndrome	1	(0.1)	1	0.05	0			
Cardiac failure	1	(0.1)	1	0.05	0			
Cardiac arrest	0				1	(0.1)	1	0.05
Myocardial infarction	0				1	(0.1)	1	0.05
Angina pectoris	0				1	(0.1)	1	0.05
Acute myocardial infarction	0				1	(0.1)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	(0.2)	4	0.21	2	(0.1)	2	0.14
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Metastases to liver	1	(0.1)	1	0.05	0			
Pancreatic neoplasm	1	(0.1)	1	0.05	0			
Adenocarcinoma pancreas	1	(0.1)	1	0.05	0			
Breast cancer metastatic	0				1	(0.1)	1	0.05
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Acute respiratory failure	1	(0.1)	1	0.09	0			
Respiratory failure	0				1	(0.1)	1	0.05
General disorders and administration site conditions	1	(0.1)	1	0.09	3	(0.2)	3	0.15
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Death	0				3	(0.2)	3	0.15
Renal and urinary disorders	1	(0.1)	2	0.18	0			
Acute kidney injury	1	(0.1)	1	0.09	0			
Chronic kidney disease	1	(0.1)	1	0.09	0			
Vascular disorders	1	(0.1)	1	0.05	0			
Arteriosclerosis	1	(0.1)	1	0.05	0			
Gastrointestinal disorders	0				1	(0.1)	1	0.09
Gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Nervous system disorders	0				1	(0.1)	1	0.09
Thrombotic stroke	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.2.33 Serious adverse events - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	166	(7.6)	245	14.82	169	(7.8)	238	13.68
Serious								
Yes	166	(7.6)	245	14.82	169	(7.8)	238	13.68
No	0				0			
Missing	0				0			
Severity								
Severe	78	(3.6)	101	6.32	71	(3.3)	98	5.41
Moderate	90	(4.1)	120	7.08	72	(3.3)	91	5.58
Mild	21	(1.0)	24	1.41	41	(1.9)	49	2.69
Missing	0				0			
Related to basal insulin								
Probable	6	(0.3)	7	0.61	1	(0.0)	1	0.04
Possible	5	(0.2)	5	0.39	8	(0.4)	9	0.64
Unlikely	159	(7.3)	233	13.82	163	(7.5)	228	12.99
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.0)	1	0.08	0			
No	166	(7.6)	244	14.74	169	(7.8)	238	13.68
NA	0				0			
Missing	0				0			
Outcome								
Fatal	14	(0.6)	18	1.17	13	(0.6)	15	0.81
Not recovered/not resolved	22	(1.0)	26	1.56	32	(1.5)	41	2.27
Recovered/resolved with sequelae	6	(0.3)	6	0.31	8	(0.4)	9	0.51
Recovering/resolving	13	(0.6)	19	1.27	15	(0.7)	17	1.07
Recovered/resolved	128	(5.9)	175	10.46	118	(5.4)	156	9.01
Unknown	1	(0.0)	1	0.04	0			
Missing	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.

7.2.34 Serious adverse events - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	155	(8.2)	230	15.48	162	(8.6)	229	14.83
Serious								
Yes	155	(8.2)	230	15.48	162	(8.6)	229	14.83
No	0				0			
Missing	0				0			
Severity								
Severe	72	(3.8)	94	6.54	69	(3.7)	95	5.93
Moderate	85	(4.5)	113	7.42	70	(3.7)	88	6.12
Mild	20	(1.1)	23	1.53	38	(2.0)	46	2.78
Missing	0				0			
Related to basal insulin								
Probable	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Possible	3	(0.2)	3	0.24	6	(0.3)	7	0.53
Unlikely	153	(8.1)	226	15.19	158	(8.4)	221	14.25
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.1)	1	0.09	0			
No	155	(8.2)	229	15.39	162	(8.6)	229	14.83
NA	0				0			
Missing	0				0			
Outcome								
Fatal	13	(0.7)	17	1.25	13	(0.7)	15	0.94
Not recovered/not resolved	21	(1.1)	25	1.70	30	(1.6)	39	2.40
Recovered/resolved with sequelae	6	(0.3)	6	0.36	8	(0.4)	9	0.59
Recovering/resolving	13	(0.7)	19	1.47	15	(0.8)	17	1.24
Recovered/resolved	119	(6.3)	162	10.66	112	(6.0)	149	9.66
Unknown	1	(0.1)	1	0.05	0			
Missing	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.

7.2.35 Serious adverse events by system organ class and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

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There is no data for this output
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7.2.36 Serious adverse events by system organ class and preferred term - most frequent [>=5%] - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

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There is no data for this output
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7.2.37 Serious adverse events by system organ class and preferred term - most frequent [>=1%] - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

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There is no data for this output
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7.2.38 Serious adverse events by system organ class and preferred term - most frequent [>=1%] - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

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There is no data for this output
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7.2.39 Serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	166	(7.6)	245	14.82	169	(7.8)	238	13.68
Infections and infestations	49	(2.3)	57	3.62	45	(2.1)	47	2.79
COVID-19 pneumonia	13	(0.6)	13	0.85	7	(0.3)	7	0.39
COVID-19	12	(0.6)	12	0.73	4	(0.2)	4	0.27
Pneumonia	8	(0.4)	8	0.50	2	(0.1)	2	0.13
Sepsis	2	(0.1)	2	0.16	1	(0.0)	1	0.05
Osteomyelitis	2	(0.1)	2	0.13	0			
Bronchitis	2	(0.1)	2	0.09	0			
Respiratory tract infection viral	1	(0.0)	1	0.09	0			
Gastroenteritis	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Paraspinal abscess	1	(0.0)	1	0.08	0			
Urinary tract infection	1	(0.0)	1	0.08	3	(0.1)	3	0.17
Cystitis	1	(0.0)	1	0.08	0			
Escherichia bacteraemia	1	(0.0)	1	0.08	0			
Influenza	1	(0.0)	1	0.08	0			
Bacteraemia	1	(0.0)	1	0.08	0			
Cholecystitis infective	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Diabetic foot infection	1	(0.0)	1	0.08	0			
Cellulitis	1	(0.0)	1	0.05	3	(0.1)	3	0.17
Erysipelas	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Respiratory syncytial virus infection	1	(0.0)	1	0.05	0			
Appendicitis	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Clostridium difficile colitis	1	(0.0)	1	0.04	0			
Gangrene	1	(0.0)	1	0.04	0			
Peritonsillar abscess	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Wound infection	1	(0.0)	1	0.04	0			
Diverticulitis	0				2	(0.1)	2	0.09
Urosepsis	0				2	(0.1)	2	0.12
Coronavirus infection	0				2	(0.1)	3	0.21
Post procedural infection	0				2	(0.1)	2	0.13
Herpes zoster infection neurological	0				1	(0.0)	1	0.04
Sweat gland infection	0				1	(0.0)	1	0.04
Anal abscess	0				1	(0.0)	1	0.05
Chronic hepatitis C	0				1	(0.0)	1	0.05
Clostridium difficile infection	0				1	(0.0)	1	0.05
Empyema	0				1	(0.0)	1	0.05
Endophthalmitis	0				1	(0.0)	1	0.05
Laryngitis	0				1	(0.0)	1	0.05
Otitis media acute	0				1	(0.0)	1	0.05
Campylobacter gastroenteritis	0				1	(0.0)	1	0.08
Herpes zoster	0				1	(0.0)	1	0.08
Soft tissue infection	0				1	(0.0)	1	0.08
Cystitis escherichia	0				1	(0.0)	1	0.09

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Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac disorders	45	(2.1)	58	3.09	31	(1.4)	40	2.22
Acute myocardial infarction	9	(0.4)	9	0.51	8	(0.4)	8	0.47
Coronary artery disease	8	(0.4)	8	0.43	8	(0.4)	8	0.43
Myocardial infarction	6	(0.3)	6	0.38	4	(0.2)	4	0.18
Atrial fibrillation	6	(0.3)	6	0.28	2	(0.1)	2	0.09
Cardiac failure	6	(0.3)	6	0.31	0			
Acute coronary syndrome	4	(0.2)	4	0.18	0			
Angina pectoris	3	(0.1)	3	0.17	2	(0.1)	2	0.13
Angina unstable	2	(0.1)	2	0.09	2	(0.1)	2	0.14
Coronary artery occlusion	2	(0.1)	2	0.09	0			
Supraventricular tachycardia	2	(0.1)	2	0.12	0			
Cardiac failure congestive	2	(0.1)	2	0.09	2	(0.1)	3	0.24
Arrhythmia	2	(0.1)	2	0.09	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Myocardial ischaemia	1	(0.0)	1	0.08	2	(0.1)	2	0.14
Atrial flutter	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Atrial thrombosis	1	(0.0)	1	0.05	0			
Chronic coronary syndrome	1	(0.0)	1	0.05	0			
Sinus tachycardia	1	(0.0)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.09
Cardiac failure acute	0				1	(0.0)	1	0.04
Coronary artery stenosis	0				1	(0.0)	1	0.04
Palpitations	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrioventricular block complete	0				1	(0.0)	1	0.05
Left ventricular dysfunction	0				1	(0.0)	1	0.05

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Serious adverse events by system organ class and preferred term - on-treatment/main-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)	15	(0.7)	18	1.05	19	(0.9)	23	1.28
Pancreatic neoplasm	2	(0.1)	2	0.13	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Colorectal cancer	2	(0.1)	2	0.12	0			
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Gastric cancer	1	(0.0)	1	0.08	0			
Lung cancer metastatic	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Small cell lung cancer	1	(0.0)	1	0.08	0			
Basal cell carcinoma	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Invasive ductal breast carcinoma	1	(0.0)	1	0.04	0			
Invasive lobular breast carcinoma	1	(0.0)	1	0.04	0			
Pancreatic carcinoma	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Benign renal neoplasm	0				1	(0.0)	1	0.04
Bowen's disease	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Invasive breast carcinoma	0				1	(0.0)	1	0.04
Malignant melanoma	0				1	(0.0)	1	0.04
Uterine leiomyoma	0				1	(0.0)	1	0.04
Small intestine neuroendocrine tumour	0				1	(0.0)	1	0.08
Uterine cancer	0				1	(0.0)	1	0.08
Colon cancer	0				1	(0.0)	1	0.05
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Malignant melanoma in situ	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Colon cancer stage II	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08

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Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injury, poisoning and procedural complications	13	(0.6)	17	0.95	17	(0.8)	18	1.06
Hip fracture	2	(0.1)	2	0.09	0			
Product administration error	1	(0.0)	1	0.09	0			
Hand fracture	1	(0.0)	1	0.08	0			
Procedural complication	1	(0.0)	1	0.08	0			
Fall	1	(0.0)	1	0.08	2	(0.1)	2	0.12
Subdural haematoma	1	(0.0)	1	0.08	0			
Fibula fracture	1	(0.0)	1	0.05	0			
Meniscus injury	1	(0.0)	1	0.05	0			
Post procedural haemorrhage	1	(0.0)	1	0.05	0			
Femoral neck fracture	1	(0.0)	1	0.04	0			
Post procedural complication	1	(0.0)	1	0.04	0			
Post procedural haematuria	1	(0.0)	1	0.04	0			
Post procedural inflammation	1	(0.0)	1	0.04	0			
Road traffic accident	1	(0.0)	1	0.04	0			
Tendon rupture	1	(0.0)	1	0.04	0			
Upper limb fracture	1	(0.0)	1	0.04	0			
Ankle fracture	0				2	(0.1)	2	0.09
Rib fracture	0				2	(0.1)	2	0.09
Periprocedural myocardial infarction	0				1	(0.0)	1	0.04
Overdose	0				1	(0.0)	1	0.08
Spinal compression fracture	0				1	(0.0)	1	0.08
Thermal burn	0				1	(0.0)	1	0.08
Deafness traumatic	0				1	(0.0)	1	0.05
Endotracheal intubation complication	0				1	(0.0)	1	0.05
Lower limb fracture	0				1	(0.0)	1	0.05
Post procedural stroke	0				1	(0.0)	1	0.05
Radius fracture	0				1	(0.0)	1	0.05
Accidental overdose	0				1	(0.0)	1	0.08
Limb injury	0				1	(0.0)	1	0.08
Tibia fracture	0				1	(0.0)	1	0.08

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Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Nervous system disorders	12	(0.6)	13	0.79	17	(0.8)	17	1.09
Transient ischaemic attack	3	(0.1)	3	0.17	1	(0.0)	1	0.05
Haemorrhage intracranial	1	(0.0)	1	0.09	0			
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Syncope	1	(0.0)	1	0.08	0			
Thalamic infarction	1	(0.0)	1	0.08	0			
Cerebral haemorrhage	1	(0.0)	1	0.05	0			
Cervical radiculopathy	1	(0.0)	1	0.05	0			
Amnesia	1	(0.0)	1	0.04	0			
Cerebral atrophy	1	(0.0)	1	0.04	0			
Cognitive disorder	1	(0.0)	1	0.04	0			
Intracranial pressure increased	1	(0.0)	1	0.04	0			
Cerebrovascular accident	0				2	(0.1)	2	0.12
Thrombotic stroke	0				2	(0.1)	2	0.13
Cerebral artery embolism	0				1	(0.0)	1	0.04
Ischaemic stroke	0				1	(0.0)	1	0.04
Loss of consciousness	0				1	(0.0)	1	0.04
Lumbar radiculopathy	0				1	(0.0)	1	0.04
White matter lesion	0				1	(0.0)	1	0.04
Carpal tunnel syndrome	0				1	(0.0)	1	0.08
Hemiparesis	0				1	(0.0)	1	0.08
Hypoglycaemic coma	0				1	(0.0)	1	0.08
Diabetic neuropathy	0				1	(0.0)	1	0.08
Cerebral infarction	0				1	(0.0)	1	0.08
Sciatica	0				1	(0.0)	1	0.08
Metabolism and nutrition disorders	9	(0.4)	11	0.90	8	(0.4)	9	0.55
Hypoglycaemia	7	(0.3)	9	0.81	3	(0.1)	3	0.17
Hyperkalaemia	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Malnutrition	1	(0.0)	1	0.04	0			
Hyperglycaemia	0				2	(0.1)	2	0.16
Gout	0				1	(0.0)	1	0.04
Lactic acidosis	0				1	(0.0)	1	0.04
Obesity	0				1	(0.0)	1	0.09
Musculoskeletal and connective tissue disorders	8	(0.4)	8	0.53	11	(0.5)	11	0.60
Back pain	2	(0.1)	2	0.13	0			
Osteoarthritis	2	(0.1)	2	0.13	2	(0.1)	2	0.09
Intervertebral disc disorder	1	(0.0)	1	0.08	0			
Intervertebral disc protrusion	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Polymyalgia rheumatica	1	(0.0)	1	0.08	0			
Plantar fasciitis	1	(0.0)	1	0.05	0			
Spinal pain	0				2	(0.1)	2	0.09
Arthritis	0				2	(0.1)	2	0.16
Arthralgia	0				1	(0.0)	1	0.04
Osteochondrosis	0				1	(0.0)	1	0.04
Rheumatoid arthritis	0				1	(0.0)	1	0.04
Trigger finger	0				1	(0.0)	1	0.04

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Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastrointestinal disorders	8	(0.4)	9	0.49	14	(0.6)	16	1.00
Vomiting	2	(0.1)	2	0.14	1	(0.0)	1	0.05
Haemorrhoids	1	(0.0)	1	0.08	1	(0.0)	1	0.09
Colitis ischaemic	1	(0.0)	1	0.05	0			
Diarrhoea	1	(0.0)	1	0.04	0			
Eosinophilic oesophagitis	1	(0.0)	1	0.04	0			
Gastric ulcer	1	(0.0)	1	0.04	0			
Inguinal hernia	1	(0.0)	1	0.04	1	(0.0)	2	0.09
Large intestine polyp	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Gastrointestinal haemorrhage	0				2	(0.1)	2	0.12
Ileus	0				1	(0.0)	1	0.04
Small intestinal obstruction	0				1	(0.0)	1	0.04
Upper gastrointestinal haemorrhage	0				1	(0.0)	1	0.08
Pancreatitis acute	0				1	(0.0)	1	0.05
Umbilical hernia	0				1	(0.0)	1	0.05
Gastritis	0				1	(0.0)	1	0.08
Gastric dysplasia	0				1	(0.0)	1	0.08
Pancreatic pseudocyst	0				1	(0.0)	1	0.08
Lumbar hernia	0				1	(0.0)	1	0.09
Renal and urinary disorders	7	(0.3)	8	0.60	9	(0.4)	11	0.57
Acute kidney injury	2	(0.1)	2	0.16	4	(0.2)	4	0.18
Ureterolithiasis	2	(0.1)	2	0.13	2	(0.1)	2	0.09
Urethral stenosis	1	(0.0)	1	0.08	0			
Renal cyst	1	(0.0)	1	0.08	0			
Renal failure	1	(0.0)	1	0.08	0			
Chronic kidney disease	1	(0.0)	1	0.08	0			
Renal colic	0				2	(0.1)	2	0.16
Nephrolithiasis	0				1	(0.0)	1	0.04
Stress urinary incontinence	0				1	(0.0)	1	0.04
Urinary tract obstruction	0				1	(0.0)	1	0.05
Vascular disorders	7	(0.3)	10	0.56	5	(0.2)	6	0.34
Peripheral artery stenosis	2	(0.1)	5	0.33	0			
Hypertensive urgency	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Peripheral arterial occlusive disease	1	(0.0)	1	0.05	0			
Peripheral artery occlusion	1	(0.0)	1	0.05	0			
Arteriosclerosis	1	(0.0)	1	0.04	0			
Venous stenosis	1	(0.0)	1	0.04	0			
Hypotension	0				1	(0.0)	1	0.04
Brachiocephalic arteriosclerosis	0				1	(0.0)	1	0.05
Iliac artery stenosis	0				1	(0.0)	1	0.05
Aortic arteriosclerosis	0				1	(0.0)	1	0.08
Haematoma	0				1	(0.0)	1	0.08

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Serious adverse events by system organ class and preferred term - on-treatment/main-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, thoracic and mediastinal disorders	6	(0.3)	6	0.37	3	(0.1)	5	0.23
Acute respiratory failure	3	(0.1)	3	0.17	1	(0.0)	1	0.05
Respiratory failure	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Dyspnoea	1	(0.0)	1	0.08	0			
Interstitial lung disease	1	(0.0)	1	0.05	0			
Pulmonary mass	0				1	(0.0)	1	0.04
Acute pulmonary oedema	0				1	(0.0)	1	0.05
Pleural effusion	0				1	(0.0)	1	0.05
Eye disorders	5	(0.2)	5	0.33	6	(0.3)	7	0.46
Cataract	2	(0.1)	2	0.12	2	(0.1)	2	0.13
Retinal vein occlusion	1	(0.0)	1	0.08	0			
Retinopathy hypertensive	1	(0.0)	1	0.08	0			
Diplopia	1	(0.0)	1	0.05	0			
Diabetic retinal oedema	0				3	(0.1)	4	0.29
Ocular ischaemic syndrome	0				1	(0.0)	1	0.04
General disorders and administration site conditions	5	(0.2)	5	0.33	6	(0.3)	8	0.36
Asthenia	1	(0.0)	1	0.08	0			
Chest discomfort	1	(0.0)	1	0.08	0			
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Drug intolerance	1	(0.0)	1	0.04	0			
Localised oedema	1	(0.0)	1	0.04	0			
Death	0				3	(0.1)	3	0.14
Non-cardiac chest pain	0				2	(0.1)	2	0.09
Pain	0				1	(0.0)	1	0.04
Peripheral swelling	0				1	(0.0)	1	0.04
Systemic inflammatory response syndrome	0				1	(0.0)	1	0.04
Reproductive system and breast disorders	3	(0.1)	3	0.19	1	(0.0)	1	0.04
Benign prostatic hyperplasia	2	(0.1)	2	0.14	1	(0.0)	1	0.04
Uterine prolapse	1	(0.0)	1	0.05	0			
Blood and lymphatic system disorders	3	(0.1)	5	0.32	2	(0.1)	2	0.09
Anaemia	3	(0.1)	5	0.32	0			
Pancytopenia	0				1	(0.0)	1	0.04
Blood loss anaemia	0				1	(0.0)	1	0.05
Skin and subcutaneous tissue disorders	3	(0.1)	3	0.17	1	(0.0)	1	0.04
Skin ulcer	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Myxoid cyst	1	(0.0)	1	0.05	0			
Urticaria	1	(0.0)	1	0.04	0			
Surgical and medical procedures	2	(0.1)	2	0.14	3	(0.1)	3	0.17
Cardiac ablation	1	(0.0)	1	0.09	0			
Cardiac pacemaker replacement	1	(0.0)	1	0.04	0			
Skin neoplasm excision	0				1	(0.0)	1	0.04
Removal of foreign body	0				1	(0.0)	1	0.05
Toe amputation	0				1	(0.0)	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.

Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Hepatobiliary disorders	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Cholelithiasis	2	(0.1)	2	0.09	0			
Bile duct stone	0				1	(0.0)	1	0.04
Hepatic cirrhosis	0				1	(0.0)	1	0.05
Immune system disorders	1	(0.0)	1	0.08	2	(0.1)	3	0.17
Anaphylactic reaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Immunisation reaction	0				1	(0.0)	2	0.09
Psychiatric disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Mental status changes	1	(0.0)	1	0.08	0			
Depression	0				1	(0.0)	1	0.08
Congenital, familial and genetic disorders	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Hydrocele	1	(0.0)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Ear and labyrinth disorders	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Vertigo positional	1	(0.0)	1	0.04	0			
Presbyacusis	0				1	(0.0)	1	0.05
Investigations	1	(0.0)	1	0.04	2	(0.1)	2	0.14
Hepatic enzyme increased	1	(0.0)	1	0.04	0			
Cardiac stress test abnormal	0				1	(0.0)	1	0.05
Blood glucose increased	0				1	(0.0)	1	0.09
Endocrine disorders	0				3	(0.1)	3	0.20
Hypothyroidism	0				1	(0.0)	1	0.04
Adrenocortical insufficiency acute	0				1	(0.0)	1	0.08
Inappropriate antidiuretic hormone secretion	0				1	(0.0)	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.

7.2.40 Serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	155	(8.2)	230	15.48	162	(8.6)	229	14.83
Infections and infestations	47	(2.5)	54	3.85	43	(2.3)	45	3.01
COVID-19 pneumonia	12	(0.6)	12	0.87	7	(0.4)	7	0.45
COVID-19	11	(0.6)	11	0.73	3	(0.2)	3	0.20
Pneumonia	8	(0.4)	8	0.58	2	(0.1)	2	0.15
Sepsis	2	(0.1)	2	0.18	1	(0.1)	1	0.05
Osteomyelitis	2	(0.1)	2	0.15	0			
Bronchitis	2	(0.1)	2	0.11	0			
Gastroenteritis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Paraspinal abscess	1	(0.1)	1	0.09	0			
Urinary tract infection	1	(0.1)	1	0.09	3	(0.2)	3	0.20
Cystitis	1	(0.1)	1	0.09	0			
Escherichia bacteraemia	1	(0.1)	1	0.09	0			
Influenza	1	(0.1)	1	0.09	0			
Bacteraemia	1	(0.1)	1	0.09	0			
Cholecystitis infective	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Diabetic foot infection	1	(0.1)	1	0.09	0			
Cellulitis	1	(0.1)	1	0.05	3	(0.2)	3	0.20
Erysipelas	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Respiratory syncytial virus infection	1	(0.1)	1	0.05	0			
Appendicitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Clostridium difficile colitis	1	(0.1)	1	0.05	0			
Gangrene	1	(0.1)	1	0.05	0			
Peritonsillar abscess	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Wound infection	1	(0.1)	1	0.05	0			
Diverticulitis	0				2	(0.1)	2	0.11
Urosepsis	0				2	(0.1)	2	0.14
Coronavirus infection	0				2	(0.1)	3	0.24
Post procedural infection	0				2	(0.1)	2	0.15
Herpes zoster infection neurological	0				1	(0.1)	1	0.05
Sweat gland infection	0				1	(0.1)	1	0.05
Anal abscess	0				1	(0.1)	1	0.05
Chronic hepatitis C	0				1	(0.1)	1	0.05
Clostridium difficile infection	0				1	(0.1)	1	0.05
Empyema	0				1	(0.1)	1	0.05
Endophthalmitis	0				1	(0.1)	1	0.05
Laryngitis	0				1	(0.1)	1	0.05
Otitis media acute	0				1	(0.1)	1	0.05
Campylobacter gastroenteritis	0				1	(0.1)	1	0.09
Herpes zoster	0				1	(0.1)	1	0.09
Soft tissue infection	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.

Serious adverse events by system organ class and preferred term - on-treatment/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	45	(2.4)	58	3.57	30	(1.6)	38	2.35
Acute myocardial infarction	9	(0.5)	9	0.59	8	(0.4)	8	0.54
Coronary artery disease	8	(0.4)	8	0.50	8	(0.4)	8	0.50
Myocardial infarction	6	(0.3)	6	0.44	4	(0.2)	4	0.21
Atrial fibrillation	6	(0.3)	6	0.32	2	(0.1)	2	0.11
Cardiac failure	6	(0.3)	6	0.35	0			
Acute coronary syndrome	4	(0.2)	4	0.21	0			
Angina pectoris	3	(0.2)	3	0.20	2	(0.1)	2	0.15
Angina unstable	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Coronary artery occlusion	2	(0.1)	2	0.11	0			
Supraventricular tachycardia	2	(0.1)	2	0.14	0			
Cardiac failure congestive	2	(0.1)	2	0.11	2	(0.1)	3	0.28
Arrhythmia	2	(0.1)	2	0.10	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Myocardial ischaemia	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Atrial flutter	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Atrial thrombosis	1	(0.1)	1	0.05	0			
Chronic coronary syndrome	1	(0.1)	1	0.05	0			
Sinus tachycardia	1	(0.1)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.10
Cardiac failure acute	0				1	(0.1)	1	0.05
Coronary artery stenosis	0				1	(0.1)	1	0.05
Palpitations	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrioventricular block complete	0				1	(0.1)	1	0.05
Left ventricular dysfunction	0				1	(0.1)	1	0.05

%: 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.

Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D 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)	15	(0.8)	18	1.21	19	(1.0)	23	1.48
Pancreatic neoplasm	2	(0.1)	2	0.15	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Colorectal cancer	2	(0.1)	2	0.14	0			
Metastases to liver	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Gastric cancer	1	(0.1)	1	0.09	0			
Lung cancer metastatic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Small cell lung cancer	1	(0.1)	1	0.09	0			
Basal cell carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Invasive ductal breast carcinoma	1	(0.1)	1	0.05	0			
Invasive lobular breast carcinoma	1	(0.1)	1	0.05	0			
Pancreatic carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Benign renal neoplasm	0				1	(0.1)	1	0.05
Bowen's disease	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Invasive breast carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma	0				1	(0.1)	1	0.05
Uterine leiomyoma	0				1	(0.1)	1	0.05
Small intestine neuroendocrine tumour	0				1	(0.1)	1	0.09
Uterine cancer	0				1	(0.1)	1	0.09
Colon cancer	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma in situ	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Colon cancer stage II	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	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.

Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injury, poisoning and procedural complications	12	(0.6)	16	0.99	17	(0.9)	18	1.22
Hip fracture	2	(0.1)	2	0.11	0			
Hand fracture	1	(0.1)	1	0.09	0			
Procedural complication	1	(0.1)	1	0.09	0			
Fall	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Subdural haematoma	1	(0.1)	1	0.09	0			
Fibula fracture	1	(0.1)	1	0.05	0			
Meniscus injury	1	(0.1)	1	0.05	0			
Post procedural haemorrhage	1	(0.1)	1	0.05	0			
Femoral neck fracture	1	(0.1)	1	0.05	0			
Post procedural complication	1	(0.1)	1	0.05	0			
Post procedural haematuria	1	(0.1)	1	0.05	0			
Post procedural inflammation	1	(0.1)	1	0.05	0			
Road traffic accident	1	(0.1)	1	0.05	0			
Tendon rupture	1	(0.1)	1	0.05	0			
Upper limb fracture	1	(0.1)	1	0.05	0			
Ankle fracture	0				2	(0.1)	2	0.10
Rib fracture	0				2	(0.1)	2	0.11
Periprocedural myocardial infarction	0				1	(0.1)	1	0.05
Overdose	0				1	(0.1)	1	0.09
Spinal compression fracture	0				1	(0.1)	1	0.09
Thermal burn	0				1	(0.1)	1	0.09
Deafness traumatic	0				1	(0.1)	1	0.05
Endotracheal intubation complication	0				1	(0.1)	1	0.05
Lower limb fracture	0				1	(0.1)	1	0.05
Post procedural stroke	0				1	(0.1)	1	0.05
Radius fracture	0				1	(0.1)	1	0.05
Accidental overdose	0				1	(0.1)	1	0.09
Limb injury	0				1	(0.1)	1	0.09
Tibia fracture	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.

Serious adverse events by system organ class and preferred term - on-treatment/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	10	(0.5)	11	0.69	16	(0.9)	16	1.15
Transient ischaemic attack	3	(0.2)	3	0.20	1	(0.1)	1	0.05
Syncope	1	(0.1)	1	0.09	0			
Thalamic infarction	1	(0.1)	1	0.09	0			
Cerebral haemorrhage	1	(0.1)	1	0.05	0			
Cervical radiculopathy	1	(0.1)	1	0.05	0			
Amnesia	1	(0.1)	1	0.05	0			
Cerebral atrophy	1	(0.1)	1	0.05	0			
Cognitive disorder	1	(0.1)	1	0.05	0			
Intracranial pressure increased	1	(0.1)	1	0.05	0			
Cerebrovascular accident	0				2	(0.1)	2	0.14
Thrombotic stroke	0				2	(0.1)	2	0.15
Cerebral artery embolism	0				1	(0.1)	1	0.05
Ischaemic stroke	0				1	(0.1)	1	0.05
Loss of consciousness	0				1	(0.1)	1	0.05
Lumbar radiculopathy	0				1	(0.1)	1	0.05
White matter lesion	0				1	(0.1)	1	0.05
Carpal tunnel syndrome	0				1	(0.1)	1	0.09
Hemiparesis	0				1	(0.1)	1	0.09
Hypoglycaemic coma	0				1	(0.1)	1	0.09
Diabetic neuropathy	0				1	(0.1)	1	0.09
Cerebral infarction	0				1	(0.1)	1	0.09
Sciatica	0				1	(0.1)	1	0.09
Musculoskeletal and connective tissue disorders	8	(0.4)	8	0.62	11	(0.6)	11	0.69
Back pain	2	(0.1)	2	0.15	0			
Osteoarthritis	2	(0.1)	2	0.15	2	(0.1)	2	0.11
Intervertebral disc disorder	1	(0.1)	1	0.09	0			
Intervertebral disc protrusion	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Polymyalgia rheumatica	1	(0.1)	1	0.09	0			
Plantar fasciitis	1	(0.1)	1	0.05	0			
Spinal pain	0				2	(0.1)	2	0.11
Arthritis	0				2	(0.1)	2	0.18
Arthralgia	0				1	(0.1)	1	0.05
Osteochondrosis	0				1	(0.1)	1	0.05
Rheumatoid arthritis	0				1	(0.1)	1	0.05
Trigger finger	0				1	(0.1)	1	0.05
Renal and urinary disorders	7	(0.4)	8	0.69	9	(0.5)	11	0.65
Acute kidney injury	2	(0.1)	2	0.18	4	(0.2)	4	0.21
Ureterolithiasis	2	(0.1)	2	0.15	2	(0.1)	2	0.11
Urethral stenosis	1	(0.1)	1	0.09	0			
Renal cyst	1	(0.1)	1	0.09	0			
Renal failure	1	(0.1)	1	0.09	0			
Chronic kidney disease	1	(0.1)	1	0.09	0			
Renal colic	0				2	(0.1)	2	0.18
Nephrolithiasis	0				1	(0.1)	1	0.05
Stress urinary incontinence	0				1	(0.1)	1	0.05
Urinary tract obstruction	0				1	(0.1)	1	0.05

%: 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.

Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Vascular disorders	7	(0.4)	10	0.65	5	(0.3)	6	0.39
Peripheral artery stenosis	2	(0.1)	5	0.39	0			
Hypertensive urgency	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Peripheral arterial occlusive disease	1	(0.1)	1	0.05	0			
Peripheral artery occlusion	1	(0.1)	1	0.05	0			
Arteriosclerosis	1	(0.1)	1	0.05	0			
Venous stenosis	1	(0.1)	1	0.05	0			
Hypotension	0				1	(0.1)	1	0.05
Brachiocephalic arteriosclerosis	0				1	(0.1)	1	0.05
Iliac artery stenosis	0				1	(0.1)	1	0.05
Aortic arteriosclerosis	0				1	(0.1)	1	0.09
Haematoma	0				1	(0.1)	1	0.09
Gastrointestinal disorders	7	(0.4)	8	0.45	12	(0.6)	14	0.94
Haemorrhoids	1	(0.1)	1	0.09	0			
Colitis ischaemic	1	(0.1)	1	0.05	0			
Diarrhoea	1	(0.1)	1	0.05	0			
Eosinophilic oesophagitis	1	(0.1)	1	0.05	0			
Gastric ulcer	1	(0.1)	1	0.05	0			
Inguinal hernia	1	(0.1)	1	0.05	1	(0.1)	2	0.11
Large intestine polyp	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Vomiting	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Gastrointestinal haemorrhage	0				2	(0.1)	2	0.14
Ileus	0				1	(0.1)	1	0.05
Small intestinal obstruction	0				1	(0.1)	1	0.05
Upper gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Pancreatitis acute	0				1	(0.1)	1	0.05
Umbilical hernia	0				1	(0.1)	1	0.05
Gastritis	0				1	(0.1)	1	0.09
Gastric dysplasia	0				1	(0.1)	1	0.09
Pancreatic pseudocyst	0				1	(0.1)	1	0.09
Respiratory, thoracic and mediastinal disorders	6	(0.3)	6	0.43	3	(0.2)	5	0.26
Acute respiratory failure	3	(0.2)	3	0.20	1	(0.1)	1	0.05
Respiratory failure	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Dyspnoea	1	(0.1)	1	0.09	0			
Interstitial lung disease	1	(0.1)	1	0.05	0			
Pulmonary mass	0				1	(0.1)	1	0.05
Acute pulmonary oedema	0				1	(0.1)	1	0.05
Pleural effusion	0				1	(0.1)	1	0.05
Eye disorders	5	(0.3)	5	0.38	6	(0.3)	7	0.53
Cataract	2	(0.1)	2	0.14	2	(0.1)	2	0.15
Retinal vein occlusion	1	(0.1)	1	0.09	0			
Retinopathy hypertensive	1	(0.1)	1	0.09	0			
Diplopia	1	(0.1)	1	0.05	0			
Diabetic retinal oedema	0				3	(0.2)	4	0.33
Ocular ischaemic syndrome	0				1	(0.1)	1	0.05

%: 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.

Serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Metabolism and nutrition disorders	5	(0.3)	5	0.38	7	(0.4)	8	0.53
Hypoglycaemia	3	(0.2)	3	0.28	3	(0.2)	3	0.19
Hyperkalaemia	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Malnutrition	1	(0.1)	1	0.05	0			
Hyperglycaemia	0				2	(0.1)	2	0.18
Gout	0				1	(0.1)	1	0.05
Lactic acidosis	0				1	(0.1)	1	0.05
General disorders and administration site conditions	5	(0.3)	5	0.38	6	(0.3)	8	0.42
Asthenia	1	(0.1)	1	0.09	0			
Chest discomfort	1	(0.1)	1	0.09	0			
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Drug intolerance	1	(0.1)	1	0.05	0			
Localised oedema	1	(0.1)	1	0.05	0			
Death	0				3	(0.2)	3	0.16
Non-cardiac chest pain	0				2	(0.1)	2	0.11
Pain	0				1	(0.1)	1	0.05
Peripheral swelling	0				1	(0.1)	1	0.05
Systemic inflammatory response syndrome	0				1	(0.1)	1	0.05
Blood and lymphatic system disorders	3	(0.2)	5	0.38	2	(0.1)	2	0.11
Anaemia	3	(0.2)	5	0.38	0			
Pancytopenia	0				1	(0.1)	1	0.05
Blood loss anaemia	0				1	(0.1)	1	0.05
Skin and subcutaneous tissue disorders	3	(0.2)	3	0.20	1	(0.1)	1	0.05
Skin ulcer	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Myxoid cyst	1	(0.1)	1	0.05	0			
Urticaria	1	(0.1)	1	0.05	0			
Reproductive system and breast disorders	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Benign prostatic hyperplasia	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Uterine prolapse	1	(0.1)	1	0.05	0			
Hepatobiliary disorders	2	(0.1)	2	0.10	2	(0.1)	2	0.11
Cholelithiasis	2	(0.1)	2	0.10	0			
Bile duct stone	0				1	(0.1)	1	0.05
Hepatic cirrhosis	0				1	(0.1)	1	0.05
Immune system disorders	1	(0.1)	1	0.09	2	(0.1)	3	0.20
Anaphylactic reaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Immunisation reaction	0				1	(0.1)	2	0.11
Psychiatric disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mental status changes	1	(0.1)	1	0.09	0			
Depression	0				1	(0.1)	1	0.09
Congenital, familial and genetic disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Hydrocele	1	(0.1)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05

%: 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.

Serious adverse events by system organ class and preferred term - on-treatment/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 and labyrinth disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Vertigo positional	1	(0.1)	1	0.05	0			
Presbyacusis	0				1	(0.1)	1	0.05
Investigations	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Hepatic enzyme increased	1	(0.1)	1	0.05	0			
Cardiac stress test abnormal	0				1	(0.1)	1	0.05
Surgical and medical procedures	1	(0.1)	1	0.05	3	(0.2)	3	0.20
Cardiac pacemaker replacement	1	(0.1)	1	0.05	0			
Skin neoplasm excision	0				1	(0.1)	1	0.05
Removal of foreign body	0				1	(0.1)	1	0.05
Toe amputation	0				1	(0.1)	1	0.09
Endocrine disorders	0				3	(0.2)	3	0.23
Hypothyroidism	0				1	(0.1)	1	0.05
Adrenocortical insufficiency acute	0				1	(0.1)	1	0.09
Inappropriate antidiuretic hormone secretion	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.

7.2.41 Serious adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	10	(0.5)	12	1.00	9	(0.4)	10	0.69
Metabolism and nutrition disorders	6	(0.3)	8	0.73	3	(0.1)	3	0.18
Hypoglycaemia	6	(0.3)	8	0.73	2	(0.1)	2	0.09
Obesity	0				1	(0.0)	1	0.09
Injury, poisoning and procedural complications	1	(0.0)	1	0.09	0			
Product administration error	1	(0.0)	1	0.09	0			
Nervous system disorders	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
General disorders and administration site conditions	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Localised oedema	1	(0.0)	1	0.04	0			
Death	0				1	(0.0)	1	0.05
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.04	0			
Urticaria	1	(0.0)	1	0.04	0			
Eye disorders	0				2	(0.1)	3	0.21
Diabetic retinal oedema	0				2	(0.1)	3	0.21
Cardiac disorders	0				1	(0.0)	1	0.08
Coronary artery disease	0				1	(0.0)	1	0.08
Immune system disorders	0				1	(0.0)	1	0.08
Anaphylactic reaction	0				1	(0.0)	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.

7.2.42 Serious adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	4	(0.2)	4	0.29	7	(0.4)	8	0.58
Metabolism and nutrition disorders	2	(0.1)	2	0.19	2	(0.1)	2	0.10
Hypoglycaemia	2	(0.1)	2	0.19	2	(0.1)	2	0.10
General disorders and administration site conditions	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Localised oedema	1	(0.1)	1	0.05	0			
Death	0				1	(0.1)	1	0.05
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	0			
Urticaria	1	(0.1)	1	0.05	0			
Eye disorders	0				2	(0.1)	3	0.24
Diabetic retinal oedema	0				2	(0.1)	3	0.24
Cardiac disorders	0				1	(0.1)	1	0.09
Coronary artery disease	0				1	(0.1)	1	0.09
Immune system disorders	0				1	(0.1)	1	0.09
Anaphylactic reaction	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.

7.2.43 Serious adverse events - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	167	(7.7)	250	14.87	170	(7.8)	241	13.73
Serious								
Yes	167	(7.7)	250	14.87	170	(7.8)	241	13.73
No	0				0			
Missing	0				0			
Severity								
Severe	80	(3.7)	104	6.39	71	(3.3)	98	5.34
Moderate	91	(4.2)	121	7.03	72	(3.3)	93	5.65
Mild	22	(1.0)	25	1.44	42	(1.9)	50	2.74
Missing	0				0			
Related to basal insulin								
Probable	6	(0.3)	7	0.60	1	(0.0)	1	0.04
Possible	5	(0.2)	5	0.39	8	(0.4)	9	0.64
Unlikely	160	(7.4)	238	13.88	164	(7.6)	231	13.05
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.0)	1	0.08	0			
No	167	(7.7)	249	14.79	170	(7.8)	241	13.73
NA	0				0			
Missing	0				0			
Outcome								
Fatal	14	(0.6)	18	1.16	13	(0.6)	15	0.80
Not recovered/not resolved	22	(1.0)	27	1.58	32	(1.5)	41	2.24
Recovered/resolved with sequelae	6	(0.3)	6	0.30	8	(0.4)	9	0.51
Recovering/resolving	14	(0.6)	21	1.37	16	(0.7)	18	1.13
Recovered/resolved	129	(5.9)	177	10.40	118	(5.4)	158	9.05
Unknown	1	(0.0)	1	0.04	0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.2.44 Serious adverse events - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	156	(8.3)	235	15.55	163	(8.7)	232	14.89
Serious								
Yes	156	(8.3)	235	15.55	163	(8.7)	232	14.89
No	0				0			
Missing	0				0			
Severity								
Severe	74	(3.9)	97	6.63	69	(3.7)	95	5.85
Moderate	86	(4.6)	114	7.37	70	(3.7)	90	6.21
Mild	21	(1.1)	24	1.56	39	(2.1)	47	2.84
Missing	0				0			
Related to basal insulin								
Probable	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Possible	3	(0.2)	3	0.23	6	(0.3)	7	0.52
Unlikely	154	(8.2)	231	15.27	159	(8.5)	224	14.32
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.1)	1	0.09	0			
No	156	(8.3)	234	15.46	163	(8.7)	232	14.89
NA	0				0			
Missing	0				0			
Outcome								
Fatal	13	(0.7)	17	1.23	13	(0.7)	15	0.92
Not recovered/not resolved	21	(1.1)	26	1.72	30	(1.6)	39	2.37
Recovered/resolved with sequelae	6	(0.3)	6	0.35	8	(0.4)	9	0.58
Recovering/resolving	14	(0.7)	21	1.59	16	(0.9)	18	1.31
Recovered/resolved	120	(6.4)	164	10.61	112	(6.0)	151	9.70
Unknown	1	(0.1)	1	0.05	0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & AESER == "Y" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:06:32 - taesum/taessumintt2dsas.txt

7.2.45 Serious adverse events by system organ class and preferred term - most frequent [>=5%] - in-trial - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & AESER == "Y" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:13 - taesocpt/taessocpt5pctsumintp3asas.txt

7.2.46 Serious adverse events by system organ class and preferred term - most frequent [>=5%] - in-trial - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                                                  AESER == "Y" & (ANL01FL) == "Y"
                                                                        nn1436/nn1436-iss/submission_20221024_er
                                                 05DEC2022:12:59:15 - taesocpt/taessocpt5pctsumintt2dsas.txt
```

7.2.47 Serious adverse events by system organ class and preferred term - most frequent [>=1%] - in-trial - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                                                  AESER == "Y" & (ANL01FL) == "Y"
                                                                        nn1436/nn1436-iss/submission_20221024_er
                                                 05DEC2022:12:59:22 - taesocpt/taessocpt1pctsumintp3asas.txt
```

7.2.48 Serious adverse events by system organ class and preferred term - most frequent [>=1%] - in-trial - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                                                  AESER == "Y" & (ANL01FL) == "Y"
                                                                        nn1436/nn1436-iss/submission_20221024_er
                                                 05DEC2022:12:59:25 - taesocpt/taessocpt1pctsumintt2dsas.txt
```

7.2.49 Serious adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	167	(7.7)	250	14.87	170	(7.8)	241	13.73
Infections and infestations	50	(2.3)	58	3.61	45	(2.1)	48	2.84
COVID-19 pneumonia	13	(0.6)	13	0.84	7	(0.3)	7	0.38
COVID-19	12	(0.6)	12	0.72	4	(0.2)	4	0.26
Pneumonia	8	(0.4)	8	0.49	2	(0.1)	2	0.12
Sepsis	3	(0.1)	3	0.20	1	(0.0)	1	0.05
Osteomyelitis	2	(0.1)	2	0.13	0			
Bronchitis	2	(0.1)	2	0.09	0			
Respiratory tract infection viral	1	(0.0)	1	0.09	0			
Gastroenteritis	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Paraspinal abscess	1	(0.0)	1	0.08	0			
Urinary tract infection	1	(0.0)	1	0.08	3	(0.1)	3	0.17
Cystitis	1	(0.0)	1	0.08	0			
Escherichia bacteraemia	1	(0.0)	1	0.08	0			
Influenza	1	(0.0)	1	0.08	0			
Bacteraemia	1	(0.0)	1	0.08	0			
Cholecystitis infective	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Diabetic foot infection	1	(0.0)	1	0.08	0			
Cellulitis	1	(0.0)	1	0.05	3	(0.1)	3	0.17
Erysipelas	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Respiratory syncytial virus infection	1	(0.0)	1	0.05	0			
Appendicitis	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Clostridium difficile colitis	1	(0.0)	1	0.04	0			
Gangrene	1	(0.0)	1	0.04	0			
Peritonsillar abscess	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Wound infection	1	(0.0)	1	0.04	0			
Diverticulitis	0				2	(0.1)	2	0.09
Urosepsis	0				2	(0.1)	2	0.12
Coronavirus infection	0				2	(0.1)	3	0.20
Post procedural infection	0				2	(0.1)	2	0.13
Herpes zoster infection neurological	0				1	(0.0)	1	0.04
Sweat gland infection	0				1	(0.0)	1	0.04
Anal abscess	0				1	(0.0)	1	0.05
Chronic hepatitis C	0				1	(0.0)	1	0.05
Clostridium difficile infection	0				1	(0.0)	1	0.05
Empyema	0				1	(0.0)	1	0.05
Endophthalmitis	0				1	(0.0)	1	0.05
Laryngitis	0				1	(0.0)	1	0.05
Otitis media acute	0				1	(0.0)	1	0.05
Campylobacter gastroenteritis	0				1	(0.0)	1	0.08
Herpes zoster	0				1	(0.0)	1	0.08
Soft tissue infection	0				1	(0.0)	1	0.08
Vulval abscess	0				1	(0.0)	1	0.08
Cystitis escherichia	0				1	(0.0)	1	0.09

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac disorders	45	(2.1)	58	3.05	31	(1.4)	40	2.20
Acute myocardial infarction	9	(0.4)	9	0.50	8	(0.4)	8	0.46
Coronary artery disease	8	(0.4)	8	0.43	8	(0.4)	8	0.42
Myocardial infarction	6	(0.3)	6	0.37	4	(0.2)	4	0.18
Atrial fibrillation	6	(0.3)	6	0.28	2	(0.1)	2	0.09
Cardiac failure	6	(0.3)	6	0.30	0			
Acute coronary syndrome	4	(0.2)	4	0.18	0			
Angina pectoris	3	(0.1)	3	0.17	2	(0.1)	2	0.13
Angina unstable	2	(0.1)	2	0.09	2	(0.1)	2	0.14
Coronary artery occlusion	2	(0.1)	2	0.09	0			
Supraventricular tachycardia	2	(0.1)	2	0.12	0			
Cardiac failure congestive	2	(0.1)	2	0.09	2	(0.1)	3	0.24
Arrhythmia	2	(0.1)	2	0.09	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Myocardial ischaemia	1	(0.0)	1	0.08	2	(0.1)	2	0.14
Atrial flutter	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Atrial thrombosis	1	(0.0)	1	0.05	0			
Chronic coronary syndrome	1	(0.0)	1	0.05	0			
Sinus tachycardia	1	(0.0)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.09
Cardiac failure acute	0				1	(0.0)	1	0.04
Coronary artery stenosis	0				1	(0.0)	1	0.04
Palpitations	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrioventricular block complete	0				1	(0.0)	1	0.05
Left ventricular dysfunction	0				1	(0.0)	1	0.05

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Serious adverse events by system organ class and preferred term - in-trial - 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)	15	(0.7)	18	1.03	19	(0.9)	23	1.26
Pancreatic neoplasm	2	(0.1)	2	0.13	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Colorectal cancer	2	(0.1)	2	0.12	0			
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Gastric cancer	1	(0.0)	1	0.08	0			
Lung cancer metastatic	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Small cell lung cancer	1	(0.0)	1	0.08	0			
Basal cell carcinoma	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Invasive ductal breast carcinoma	1	(0.0)	1	0.04	0			
Invasive lobular breast carcinoma	1	(0.0)	1	0.04	0			
Pancreatic carcinoma	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Benign renal neoplasm	0				1	(0.0)	1	0.04
Bowen's disease	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Invasive breast carcinoma	0				1	(0.0)	1	0.04
Malignant melanoma	0				1	(0.0)	1	0.04
Uterine leiomyoma	0				1	(0.0)	1	0.04
Small intestine neuroendocrine tumour	0				1	(0.0)	1	0.08
Uterine cancer	0				1	(0.0)	1	0.08
Colon cancer	0				1	(0.0)	1	0.05
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Malignant melanoma in situ	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Colon cancer stage II	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Nervous system disorders	14	(0.6)	15	0.86	17	(0.8)	17	1.07
Transient ischaemic attack	3	(0.1)	3	0.17	1	(0.0)	1	0.05
Haemorrhage intracranial	1	(0.0)	1	0.09	0			
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Syncope	1	(0.0)	1	0.08	0			
Thalamic infarction	1	(0.0)	1	0.08	0			
Cerebral haemorrhage	1	(0.0)	1	0.05	0			
Cervical radiculopathy	1	(0.0)	1	0.05	0			
Amnesia	1	(0.0)	1	0.04	0			
Cerebral atrophy	1	(0.0)	1	0.04	0			
Cerebral ischaemia	1	(0.0)	1	0.04	0			
Cognitive disorder	1	(0.0)	1	0.04	0			
Hypoglycaemic unconsciousness	1	(0.0)	1	0.04	0			
Intracranial pressure increased	1	(0.0)	1	0.04	0			
Cerebrovascular accident	0				2	(0.1)	2	0.12
Thrombotic stroke	0				2	(0.1)	2	0.12
Cerebral artery embolism	0				1	(0.0)	1	0.04
Ischaemic stroke	0				1	(0.0)	1	0.04
Loss of consciousness	0				1	(0.0)	1	0.04
Lumbar radiculopathy	0				1	(0.0)	1	0.04
White matter lesion	0				1	(0.0)	1	0.04
Carpal tunnel syndrome	0				1	(0.0)	1	0.08
Hemiparesis	0				1	(0.0)	1	0.08
Hypoglycaemic coma	0				1	(0.0)	1	0.08
Diabetic neuropathy	0				1	(0.0)	1	0.08
Cerebral infarction	0				1	(0.0)	1	0.08
Sciatica	0				1	(0.0)	1	0.08

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injury, poisoning and procedural complications	13	(0.6)	17	0.94	17	(0.8)	18	1.05
Hip fracture	2	(0.1)	2	0.09	0			
Product administration error	1	(0.0)	1	0.09	0			
Hand fracture	1	(0.0)	1	0.08	0			
Procedural complication	1	(0.0)	1	0.08	0			
Fall	1	(0.0)	1	0.08	2	(0.1)	2	0.12
Subdural haematoma	1	(0.0)	1	0.08	0			
Fibula fracture	1	(0.0)	1	0.05	0			
Meniscus injury	1	(0.0)	1	0.05	0			
Post procedural haemorrhage	1	(0.0)	1	0.05	0			
Femoral neck fracture	1	(0.0)	1	0.04	0			
Post procedural complication	1	(0.0)	1	0.04	0			
Post procedural haematuria	1	(0.0)	1	0.04	0			
Post procedural inflammation	1	(0.0)	1	0.04	0			
Road traffic accident	1	(0.0)	1	0.04	0			
Tendon rupture	1	(0.0)	1	0.04	0			
Upper limb fracture	1	(0.0)	1	0.04	0			
Ankle fracture	0				2	(0.1)	2	0.09
Rib fracture	0				2	(0.1)	2	0.09
Periprocedural myocardial infarction	0				1	(0.0)	1	0.04
Overdose	0				1	(0.0)	1	0.08
Spinal compression fracture	0				1	(0.0)	1	0.08
Thermal burn	0				1	(0.0)	1	0.08
Deafness traumatic	0				1	(0.0)	1	0.05
Endotracheal intubation complication	0				1	(0.0)	1	0.05
Lower limb fracture	0				1	(0.0)	1	0.05
Post procedural stroke	0				1	(0.0)	1	0.05
Radius fracture	0				1	(0.0)	1	0.05
Accidental overdose	0				1	(0.0)	1	0.08
Limb injury	0				1	(0.0)	1	0.08
Tibia fracture	0				1	(0.0)	1	0.08
Metabolism and nutrition disorders	9	(0.4)	11	0.89	8	(0.4)	9	0.54
Hypoglycaemia	7	(0.3)	9	0.80	3	(0.1)	3	0.17
Hyperkalaemia	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Malnutrition	1	(0.0)	1	0.04	0			
Hyperglycaemia	0				2	(0.1)	2	0.16
Gout	0				1	(0.0)	1	0.04
Lactic acidosis	0				1	(0.0)	1	0.04
Obesity	0				1	(0.0)	1	0.09
Musculoskeletal and connective tissue disorders	8	(0.4)	8	0.53	11	(0.5)	11	0.59
Back pain	2	(0.1)	2	0.13	0			
Osteoarthritis	2	(0.1)	2	0.13	2	(0.1)	2	0.09
Intervertebral disc disorder	1	(0.0)	1	0.08	0			
Intervertebral disc protrusion	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Polymyalgia rheumatica	1	(0.0)	1	0.08	0			
Plantar fasciitis	1	(0.0)	1	0.05	0			
Spinal pain	0				2	(0.1)	2	0.09
Arthritis	0				2	(0.1)	2	0.16
Arthralgia	0				1	(0.0)	1	0.04
Osteochondrosis	0				1	(0.0)	1	0.04
Rheumatoid arthritis	0				1	(0.0)	1	0.04
Trigger finger	0				1	(0.0)	1	0.04

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastrointestinal disorders	8	(0.4)	10	0.52	15	(0.7)	17	1.06
Vomiting	2	(0.1)	2	0.14	1	(0.0)	1	0.05
Haemorrhoids	1	(0.0)	1	0.08	1	(0.0)	1	0.09
Colitis ischaemic	1	(0.0)	1	0.05	0			
Abdominal discomfort	1	(0.0)	1	0.04	0			
Diarrhoea	1	(0.0)	1	0.04	0			
Eosinophilic oesophagitis	1	(0.0)	1	0.04	0			
Gastric ulcer	1	(0.0)	1	0.04	0			
Inguinal hernia	1	(0.0)	1	0.04	1	(0.0)	2	0.09
Large intestine polyp	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Gastrointestinal haemorrhage	0				2	(0.1)	2	0.12
Umbilical hernia	0				2	(0.1)	2	0.12
Ileus	0				1	(0.0)	1	0.04
Small intestinal obstruction	0				1	(0.0)	1	0.04
Upper gastrointestinal haemorrhage	0				1	(0.0)	1	0.08
Pancreatitis acute	0				1	(0.0)	1	0.05
Gastritis	0				1	(0.0)	1	0.08
Gastric dysplasia	0				1	(0.0)	1	0.08
Pancreatic pseudocyst	0				1	(0.0)	1	0.08
Lumbar hernia	0				1	(0.0)	1	0.09
Renal and urinary disorders	7	(0.3)	8	0.59	9	(0.4)	11	0.56
Acute kidney injury	2	(0.1)	2	0.16	4	(0.2)	4	0.18
Ureterolithiasis	2	(0.1)	2	0.12	2	(0.1)	2	0.09
Urethral stenosis	1	(0.0)	1	0.08	0			
Renal cyst	1	(0.0)	1	0.08	0			
Renal failure	1	(0.0)	1	0.08	0			
Chronic kidney disease	1	(0.0)	1	0.08	0			
Renal colic	0				2	(0.1)	2	0.16
Nephrolithiasis	0				1	(0.0)	1	0.04
Stress urinary incontinence	0				1	(0.0)	1	0.04
Urinary tract obstruction	0				1	(0.0)	1	0.05
Respiratory, thoracic and mediastinal disorders	7	(0.3)	7	0.45	3	(0.1)	5	0.23
Acute respiratory failure	3	(0.1)	3	0.17	1	(0.0)	1	0.05
Pulmonary embolism	1	(0.0)	1	0.08	0			
Respiratory failure	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Dyspnoea	1	(0.0)	1	0.08	0			
Interstitial lung disease	1	(0.0)	1	0.05	0			
Pulmonary mass	0				1	(0.0)	1	0.04
Acute pulmonary oedema	0				1	(0.0)	1	0.05
Pleural effusion	0				1	(0.0)	1	0.05
Vascular disorders	7	(0.3)	10	0.56	5	(0.2)	6	0.34
Peripheral artery stenosis	2	(0.1)	5	0.33	0			
Hypertensive urgency	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Peripheral arterial occlusive disease	1	(0.0)	1	0.05	0			
Peripheral artery occlusion	1	(0.0)	1	0.05	0			
Arteriosclerosis	1	(0.0)	1	0.04	0			
Venous stenosis	1	(0.0)	1	0.04	0			
Hypotension	0				1	(0.0)	1	0.04
Brachiocephalic arteriosclerosis	0				1	(0.0)	1	0.05
Iliac artery stenosis	0				1	(0.0)	1	0.05
Aortic arteriosclerosis	0				1	(0.0)	1	0.08
Haematoma	0				1	(0.0)	1	0.08

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Eye disorders	5	(0.2)	5	0.33	6	(0.3)	7	0.45
Cataract	2	(0.1)	2	0.12	2	(0.1)	2	0.13
Retinal vein occlusion	1	(0.0)	1	0.08	0			
Retinopathy hypertensive	1	(0.0)	1	0.08	0			
Diplopia	1	(0.0)	1	0.05	0			
Diabetic retinal oedema	0				3	(0.1)	4	0.28
Ocular ischaemic syndrome	0				1	(0.0)	1	0.04
General disorders and administration site conditions	5	(0.2)	5	0.32	6	(0.3)	8	0.35
Asthenia	1	(0.0)	1	0.08	0			
Chest discomfort	1	(0.0)	1	0.08	0			
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Drug intolerance	1	(0.0)	1	0.04	0			
Localised oedema	1	(0.0)	1	0.04	0			
Death	0				3	(0.1)	3	0.13
Non-cardiac chest pain	0				2	(0.1)	2	0.09
Pain	0				1	(0.0)	1	0.04
Peripheral swelling	0				1	(0.0)	1	0.04
Systemic inflammatory response syndrome	0				1	(0.0)	1	0.04
Reproductive system and breast disorders	3	(0.1)	3	0.19	1	(0.0)	1	0.04
Benign prostatic hyperplasia	2	(0.1)	2	0.14	1	(0.0)	1	0.04
Uterine prolapse	1	(0.0)	1	0.05	0			
Blood and lymphatic system disorders	3	(0.1)	5	0.32	2	(0.1)	2	0.09
Anaemia	3	(0.1)	5	0.32	0			
Pancytopenia	0				1	(0.0)	1	0.04
Blood loss anaemia	0				1	(0.0)	1	0.05
Skin and subcutaneous tissue disorders	3	(0.1)	3	0.17	1	(0.0)	1	0.04
Skin ulcer	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Myxoid cyst	1	(0.0)	1	0.05	0			
Urticaria	1	(0.0)	1	0.04	0			
Surgical and medical procedures	2	(0.1)	2	0.14	3	(0.1)	3	0.17
Cardiac ablation	1	(0.0)	1	0.09	0			
Cardiac pacemaker replacement	1	(0.0)	1	0.04	0			
Skin neoplasm excision	0				1	(0.0)	1	0.04
Removal of foreign body	0				1	(0.0)	1	0.05
Toe amputation	0				1	(0.0)	1	0.08
Hepatobiliary disorders	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Cholelithiasis	2	(0.1)	2	0.09	0			
Bile duct stone	0				1	(0.0)	1	0.04
Hepatic cirrhosis	0				1	(0.0)	1	0.05
Immune system disorders	1	(0.0)	1	0.08	2	(0.1)	3	0.17
Anaphylactic reaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Immunisation reaction	0				1	(0.0)	2	0.09
Psychiatric disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Mental status changes	1	(0.0)	1	0.08	0			
Depression	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

Serious adverse events by system organ class and preferred term - in-trial - 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	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Hydrocele	1	(0.0)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Ear and labyrinth disorders	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Vertigo positional	1	(0.0)	1	0.04	0			
Presbyacusis	0				1	(0.0)	1	0.05
Investigations	1	(0.0)	1	0.04	2	(0.1)	2	0.14
Hepatic enzyme increased	1	(0.0)	1	0.04	0			
Cardiac stress test abnormal	0				1	(0.0)	1	0.05
Blood glucose increased	0				1	(0.0)	1	0.09
Endocrine disorders	0				3	(0.1)	4	0.28
Hypothyroidism	0				1	(0.0)	1	0.04
Adrenocortical insufficiency acute	0				1	(0.0)	2	0.16
Inappropriate antidiuretic hormone secretion	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.2.50 Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	156	(8.3)	235	15.55	163	(8.7)	232	14.89
Infections and infestations	48	(2.6)	55	3.85	43	(2.3)	46	3.06
COVID-19 pneumonia	12	(0.6)	12	0.86	7	(0.4)	7	0.44
COVID-19	11	(0.6)	11	0.72	3	(0.2)	3	0.20
Pneumonia	8	(0.4)	8	0.57	2	(0.1)	2	0.14
Sepsis	3	(0.2)	3	0.23	1	(0.1)	1	0.05
Osteomyelitis	2	(0.1)	2	0.14	0			
Bronchitis	2	(0.1)	2	0.10	0			
Gastroenteritis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Paraspinal abscess	1	(0.1)	1	0.09	0			
Urinary tract infection	1	(0.1)	1	0.09	3	(0.2)	3	0.20
Cystitis	1	(0.1)	1	0.09	0			
Escherichia bacteraemia	1	(0.1)	1	0.09	0			
Influenza	1	(0.1)	1	0.09	0			
Bacteraemia	1	(0.1)	1	0.09	0			
Cholecystitis infective	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Diabetic foot infection	1	(0.1)	1	0.09	0			
Cellulitis	1	(0.1)	1	0.05	3	(0.2)	3	0.19
Erysipelas	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Respiratory syncytial virus infection	1	(0.1)	1	0.05	0			
Appendicitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Clostridium difficile colitis	1	(0.1)	1	0.05	0			
Gangrene	1	(0.1)	1	0.05	0			
Peritonsillar abscess	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Wound infection	1	(0.1)	1	0.05	0			
Diverticulitis	0				2	(0.1)	2	0.10
Urosepsis	0				2	(0.1)	2	0.14
Coronavirus infection	0				2	(0.1)	3	0.24
Post procedural infection	0				2	(0.1)	2	0.14
Herpes zoster infection neurological	0				1	(0.1)	1	0.05
Sweat gland infection	0				1	(0.1)	1	0.05
Anal abscess	0				1	(0.1)	1	0.05
Chronic hepatitis C	0				1	(0.1)	1	0.05
Clostridium difficile infection	0				1	(0.1)	1	0.05
Empyema	0				1	(0.1)	1	0.05
Endophthalmitis	0				1	(0.1)	1	0.05
Laryngitis	0				1	(0.1)	1	0.05
Otitis media acute	0				1	(0.1)	1	0.05
Campylobacter gastroenteritis	0				1	(0.1)	1	0.09
Herpes zoster	0				1	(0.1)	1	0.09
Soft tissue infection	0				1	(0.1)	1	0.09
Vulval abscess	0				1	(0.1)	1	0.09

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac disorders	45	(2.4)	58	3.52	30	(1.6)	38	2.32
Acute myocardial infarction	9	(0.5)	9	0.58	8	(0.4)	8	0.54
Coronary artery disease	8	(0.4)	8	0.49	8	(0.4)	8	0.49
Myocardial infarction	6	(0.3)	6	0.43	4	(0.2)	4	0.21
Atrial fibrillation	6	(0.3)	6	0.32	2	(0.1)	2	0.11
Cardiac failure	6	(0.3)	6	0.35	0			
Acute coronary syndrome	4	(0.2)	4	0.21	0			
Angina pectoris	3	(0.2)	3	0.19	2	(0.1)	2	0.14
Angina unstable	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Coronary artery occlusion	2	(0.1)	2	0.11	0			
Supraventricular tachycardia	2	(0.1)	2	0.14	0			
Cardiac failure congestive	2	(0.1)	2	0.10	2	(0.1)	3	0.27
Arrhythmia	2	(0.1)	2	0.10	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Myocardial ischaemia	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Atrial flutter	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Atrial thrombosis	1	(0.1)	1	0.05	0			
Chronic coronary syndrome	1	(0.1)	1	0.05	0			
Sinus tachycardia	1	(0.1)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.10
Cardiac failure acute	0				1	(0.1)	1	0.05
Coronary artery stenosis	0				1	(0.1)	1	0.05
Palpitations	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrioventricular block complete	0				1	(0.1)	1	0.05
Left ventricular dysfunction	0				1	(0.1)	1	0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D 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)	15	(0.8)	18	1.19	19	(1.0)	23	1.45
Pancreatic neoplasm	2	(0.1)	2	0.14	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Colorectal cancer	2	(0.1)	2	0.14	0			
Metastases to liver	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Gastric cancer	1	(0.1)	1	0.09	0			
Lung cancer metastatic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Small cell lung cancer	1	(0.1)	1	0.09	0			
Basal cell carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Invasive ductal breast carcinoma	1	(0.1)	1	0.05	0			
Invasive lobular breast carcinoma	1	(0.1)	1	0.05	0			
Pancreatic carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Benign renal neoplasm	0				1	(0.1)	1	0.05
Bowen's disease	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Invasive breast carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma	0				1	(0.1)	1	0.05
Uterine leiomyoma	0				1	(0.1)	1	0.05
Small intestine neuroendocrine tumour	0				1	(0.1)	1	0.09
Uterine cancer	0				1	(0.1)	1	0.09
Colon cancer	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma in situ	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Colon cancer stage II	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Injury, poisoning and procedural complications	12	(0.6)	16	0.98	17	(0.9)	18	1.21
Hip fracture	2	(0.1)	2	0.10	0			
Hand fracture	1	(0.1)	1	0.09	0			
Procedural complication	1	(0.1)	1	0.09	0			
Fall	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Subdural haematoma	1	(0.1)	1	0.09	0			
Fibula fracture	1	(0.1)	1	0.05	0			
Meniscus injury	1	(0.1)	1	0.05	0			
Post procedural haemorrhage	1	(0.1)	1	0.05	0			
Femoral neck fracture	1	(0.1)	1	0.05	0			
Post procedural complication	1	(0.1)	1	0.05	0			
Post procedural haematuria	1	(0.1)	1	0.05	0			
Post procedural inflammation	1	(0.1)	1	0.05	0			
Road traffic accident	1	(0.1)	1	0.05	0			
Tendon rupture	1	(0.1)	1	0.05	0			
Upper limb fracture	1	(0.1)	1	0.05	0			
Ankle fracture	0				2	(0.1)	2	0.10
Rib fracture	0				2	(0.1)	2	0.10
Periprocedural myocardial infarction	0				1	(0.1)	1	0.05
Overdose	0				1	(0.1)	1	0.09
Spinal compression fracture	0				1	(0.1)	1	0.09
Thermal burn	0				1	(0.1)	1	0.09
Deafness traumatic	0				1	(0.1)	1	0.05
Endotracheal intubation complication	0				1	(0.1)	1	0.05
Lower limb fracture	0				1	(0.1)	1	0.05
Post procedural stroke	0				1	(0.1)	1	0.05
Radius fracture	0				1	(0.1)	1	0.05
Accidental overdose	0				1	(0.1)	1	0.09
Limb injury	0				1	(0.1)	1	0.09
Tibia fracture	0				1	(0.1)	1	0.09
Nervous system disorders	12	(0.6)	13	0.78	16	(0.9)	16	1.13
Transient ischaemic attack	3	(0.2)	3	0.19	1	(0.1)	1	0.05
Syncope	1	(0.1)	1	0.09	0			
Thalamic infarction	1	(0.1)	1	0.09	0			
Cerebral haemorrhage	1	(0.1)	1	0.05	0			
Cervical radiculopathy	1	(0.1)	1	0.05	0			
Amnesia	1	(0.1)	1	0.05	0			
Cerebral atrophy	1	(0.1)	1	0.05	0			
Cerebral ischaemia	1	(0.1)	1	0.05	0			
Cognitive disorder	1	(0.1)	1	0.05	0			
Hypoglycaemic unconsciousness	1	(0.1)	1	0.05	0			
Intracranial pressure increased	1	(0.1)	1	0.05	0			
Cerebrovascular accident	0				2	(0.1)	2	0.14
Thrombotic stroke	0				2	(0.1)	2	0.14
Cerebral artery embolism	0				1	(0.1)	1	0.05
Ischaemic stroke	0				1	(0.1)	1	0.05
Loss of consciousness	0				1	(0.1)	1	0.05
Lumbar radiculopathy	0				1	(0.1)	1	0.05
White matter lesion	0				1	(0.1)	1	0.05
Carpal tunnel syndrome	0				1	(0.1)	1	0.09
Hemiparesis	0				1	(0.1)	1	0.09
Hypoglycaemic coma	0				1	(0.1)	1	0.09
Diabetic neuropathy	0				1	(0.1)	1	0.09
Cerebral infarction	0				1	(0.1)	1	0.09
Sciatica	0				1	(0.1)	1	0.09

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Musculoskeletal and connective tissue disorders	8	(0.4)	8	0.61	11	(0.6)	11	0.68
Back pain	2	(0.1)	2	0.14	0			
Osteoarthritis	2	(0.1)	2	0.14	2	(0.1)	2	0.10
Intervertebral disc disorder	1	(0.1)	1	0.09	0			
Intervertebral disc protrusion	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Polymyalgia rheumatica	1	(0.1)	1	0.09	0			
Plantar fasciitis	1	(0.1)	1	0.05	0			
Spinal pain	0				2	(0.1)	2	0.11
Arthritis	0				2	(0.1)	2	0.18
Arthralgia	0				1	(0.1)	1	0.05
Osteochondrosis	0				1	(0.1)	1	0.05
Rheumatoid arthritis	0				1	(0.1)	1	0.05
Trigger finger	0				1	(0.1)	1	0.05
Renal and urinary disorders	7	(0.4)	8	0.69	9	(0.5)	11	0.64
Acute kidney injury	2	(0.1)	2	0.18	4	(0.2)	4	0.20
Ureterolithiasis	2	(0.1)	2	0.14	2	(0.1)	2	0.10
Urethral stenosis	1	(0.1)	1	0.09	0			
Renal cyst	1	(0.1)	1	0.09	0			
Renal failure	1	(0.1)	1	0.09	0			
Chronic kidney disease	1	(0.1)	1	0.09	0			
Renal colic	0				2	(0.1)	2	0.18
Nephrolithiasis	0				1	(0.1)	1	0.05
Stress urinary incontinence	0				1	(0.1)	1	0.05
Urinary tract obstruction	0				1	(0.1)	1	0.05
Respiratory, thoracic and mediastinal disorders	7	(0.4)	7	0.51	3	(0.2)	5	0.26
Acute respiratory failure	3	(0.2)	3	0.19	1	(0.1)	1	0.05
Pulmonary embolism	1	(0.1)	1	0.09	0			
Respiratory failure	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Dyspnoea	1	(0.1)	1	0.09	0			
Interstitial lung disease	1	(0.1)	1	0.05	0			
Pulmonary mass	0				1	(0.1)	1	0.05
Acute pulmonary oedema	0				1	(0.1)	1	0.05
Pleural effusion	0				1	(0.1)	1	0.05
Vascular disorders	7	(0.4)	10	0.64	5	(0.3)	6	0.39
Peripheral artery stenosis	2	(0.1)	5	0.38	0			
Hypertensive urgency	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Peripheral arterial occlusive disease	1	(0.1)	1	0.05	0			
Peripheral artery occlusion	1	(0.1)	1	0.05	0			
Arteriosclerosis	1	(0.1)	1	0.05	0			
Venous stenosis	1	(0.1)	1	0.05	0			
Hypotension	0				1	(0.1)	1	0.05
Brachiocephalic arteriosclerosis	0				1	(0.1)	1	0.05
Iliac artery stenosis	0				1	(0.1)	1	0.05
Aortic arteriosclerosis	0				1	(0.1)	1	0.09
Haematoma	0				1	(0.1)	1	0.09

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Serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastrointestinal disorders	7	(0.4)	9	0.49	13	(0.7)	15	1.02
Haemorrhoids	1	(0.1)	1	0.09	0			
Colitis ischaemic	1	(0.1)	1	0.05	0			
Abdominal discomfort	1	(0.1)	1	0.05	0			
Diarrhoea	1	(0.1)	1	0.05	0			
Eosinophilic oesophagitis	1	(0.1)	1	0.05	0			
Gastric ulcer	1	(0.1)	1	0.05	0			
Inguinal hernia	1	(0.1)	1	0.05	1	(0.1)	2	0.11
Large intestine polyp	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Vomiting	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Gastrointestinal haemorrhage	0				2	(0.1)	2	0.14
Umbilical hernia	0				2	(0.1)	2	0.14
Ileus	0				1	(0.1)	1	0.05
Small intestinal obstruction	0				1	(0.1)	1	0.05
Upper gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Pancreatitis acute	0				1	(0.1)	1	0.05
Gastritis	0				1	(0.1)	1	0.09
Gastric dysplasia	0				1	(0.1)	1	0.09
Pancreatic pseudocyst	0				1	(0.1)	1	0.09
Eye disorders	5	(0.3)	5	0.38	6	(0.3)	7	0.52
Cataract	2	(0.1)	2	0.14	2	(0.1)	2	0.14
Retinal vein occlusion	1	(0.1)	1	0.09	0			
Retinopathy hypertensive	1	(0.1)	1	0.09	0			
Diplopia	1	(0.1)	1	0.05	0			
Diabetic retinal oedema	0				3	(0.2)	4	0.33
Ocular ischaemic syndrome	0				1	(0.1)	1	0.05
Metabolism and nutrition disorders	5	(0.3)	5	0.38	7	(0.4)	8	0.52
Hypoglycaemia	3	(0.2)	3	0.27	3	(0.2)	3	0.19
Hyperkalaemia	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Malnutrition	1	(0.1)	1	0.05	0			
Hyperglycaemia	0				2	(0.1)	2	0.18
Gout	0				1	(0.1)	1	0.05
Lactic acidosis	0				1	(0.1)	1	0.05
General disorders and administration site conditions	5	(0.3)	5	0.37	6	(0.3)	8	0.41
Asthenia	1	(0.1)	1	0.09	0			
Chest discomfort	1	(0.1)	1	0.09	0			
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Drug intolerance	1	(0.1)	1	0.05	0			
Localised oedema	1	(0.1)	1	0.05	0			
Death	0				3	(0.2)	3	0.15
Non-cardiac chest pain	0				2	(0.1)	2	0.10
Pain	0				1	(0.1)	1	0.05
Peripheral swelling	0				1	(0.1)	1	0.05
Systemic inflammatory response syndrome	0				1	(0.1)	1	0.05
Blood and lymphatic system disorders	3	(0.2)	5	0.37	2	(0.1)	2	0.10
Anaemia	3	(0.2)	5	0.37	0			
Pancytopenia	0				1	(0.1)	1	0.05
Blood loss anaemia	0				1	(0.1)	1	0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

Serious adverse events by system organ class and preferred term - in-trial - 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	3	(0.2)	3	0.19	1	(0.1)	1	0.05
Skin ulcer	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Myxoid cyst	1	(0.1)	1	0.05	0			
Urticaria	1	(0.1)	1	0.05	0			
Reproductive system and breast disorders	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Benign prostatic hyperplasia	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Uterine prolapse	1	(0.1)	1	0.05	0			
Hepatobiliary disorders	2	(0.1)	2	0.10	2	(0.1)	2	0.10
Cholelithiasis	2	(0.1)	2	0.10	0			
Bile duct stone	0				1	(0.1)	1	0.05
Hepatic cirrhosis	0				1	(0.1)	1	0.05
Immune system disorders	1	(0.1)	1	0.09	2	(0.1)	3	0.20
Anaphylactic reaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Immunisation reaction	0				1	(0.1)	2	0.11
Psychiatric disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Mental status changes	1	(0.1)	1	0.09	0			
Depression	0				1	(0.1)	1	0.09
Congenital, familial and genetic disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Hydrocele	1	(0.1)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05
Ear and labyrinth disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Vertigo positional	1	(0.1)	1	0.05	0			
Presbyacusis	0				1	(0.1)	1	0.05
Investigations	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Hepatic enzyme increased	1	(0.1)	1	0.05	0			
Cardiac stress test abnormal	0				1	(0.1)	1	0.05
Surgical and medical procedures	1	(0.1)	1	0.05	3	(0.2)	3	0.19
Cardiac pacemaker replacement	1	(0.1)	1	0.05	0			
Skin neoplasm excision	0				1	(0.1)	1	0.05
Removal of foreign body	0				1	(0.1)	1	0.05
Toe amputation	0				1	(0.1)	1	0.09
Endocrine disorders	0				3	(0.2)	4	0.32
Hypothyroidism	0				1	(0.1)	1	0.05
Adrenocortical insufficiency acute	0				1	(0.1)	2	0.18
Inappropriate antidiuretic hormone secretion	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.2.51 Serious adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	10	(0.5)	12	0.99	9	(0.4)	10	0.68
Metabolism and nutrition disorders	6	(0.3)	8	0.72	3	(0.1)	3	0.18
Hypoglycaemia	6	(0.3)	8	0.72	2	(0.1)	2	0.09
Obesity	0				1	(0.0)	1	0.09
Injury, poisoning and procedural complications	1	(0.0)	1	0.09	0			
Product administration error	1	(0.0)	1	0.09	0			
Nervous system disorders	1	(0.0)	1	0.09	1	(0.0)	1	0.09
Hypoglycaemic seizure	1	(0.0)	1	0.09	1	(0.0)	1	0.09
General disorders and administration site conditions	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Localised oedema	1	(0.0)	1	0.04	0			
Death	0				1	(0.0)	1	0.05
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.04	0			
Urticaria	1	(0.0)	1	0.04	0			
Eye disorders	0				2	(0.1)	3	0.20
Diabetic retinal oedema	0				2	(0.1)	3	0.20
Cardiac disorders	0				1	(0.0)	1	0.08
Coronary artery disease	0				1	(0.0)	1	0.08
Immune system disorders	0				1	(0.0)	1	0.08
Anaphylactic reaction	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.2.52 Serious adverse events possibly or probably related to insulin icodec or daily basal insulin by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	4	(0.2)	4	0.28	7	(0.4)	8	0.57
Metabolism and nutrition disorders	2	(0.1)	2	0.18	2	(0.1)	2	0.10
Hypoglycaemia	2	(0.1)	2	0.18	2	(0.1)	2	0.10
General disorders and administration site conditions	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Localised oedema	1	(0.1)	1	0.05	0			
Death	0				1	(0.1)	1	0.05
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	0			
Urticaria	1	(0.1)	1	0.05	0			
Eye disorders	0				2	(0.1)	3	0.24
Diabetic retinal oedema	0				2	(0.1)	3	0.24
Cardiac disorders	0				1	(0.1)	1	0.09
Coronary artery disease	0				1	(0.1)	1	0.09
Immune system disorders	0				1	(0.1)	1	0.09
Anaphylactic reaction	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. MedDRA version 24.1. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.2.53 Adverse events leading to permanent discontinuation of insulin icodec or daily basal insulin - on- treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	21	(1.0)	27	1.53	19	(0.9)	24	1.48
Serious								
Yes	10	(0.5)	14	0.77	13	(0.6)	14	0.80
No	12	(0.6)	13	0.76	7	(0.3)	10	0.67
Missing	0				0			
Severity								
Severe	10	(0.5)	12	0.71	12	(0.6)	13	0.76
Moderate	6	(0.3)	7	0.39	5	(0.2)	5	0.30
Mild	7	(0.3)	8	0.43	4	(0.2)	6	0.42
Missing	0				0			
Related to basal insulin								
Probable	6	(0.3)	8	0.43	0			
Possible	2	(0.1)	2	0.13	4	(0.2)	4	0.22
Unlikely	13	(0.6)	17	0.97	15	(0.7)	20	1.26
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	21	(1.0)	27	1.53	19	(0.9)	24	1.48
NA	0				0			
Missing	0				0			
Outcome								
Fatal	5	(0.2)	6	0.34	5	(0.2)	6	0.34
Not recovered/not resolved	9	(0.4)	9	0.58	7	(0.3)	10	0.67
Recovered/resolved with sequelae	0				0			
Recovering/resolving	2	(0.1)	2	0.12	2	(0.1)	2	0.12
Recovered/resolved	6	(0.3)	10	0.48	6	(0.3)	6	0.34
Unknown	0				0			
Missing	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.

7.2.54 Adverse events leading to permanent discontinuation of insulin icodec or daily basal insulin - on- treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	21	(1.1)	27	1.76	18	(1.0)	23	1.60
Serious								
Yes	10	(0.5)	14	0.89	13	(0.7)	14	0.93
No	12	(0.6)	13	0.87	6	(0.3)	9	0.67
Missing	0				0			
Severity								
Severe	10	(0.5)	12	0.82	12	(0.6)	13	0.88
Moderate	6	(0.3)	7	0.45	5	(0.3)	5	0.34
Mild	7	(0.4)	8	0.50	3	(0.2)	5	0.38
Missing	0				0			
Related to basal insulin								
Probable	6	(0.3)	8	0.49	0			
Possible	2	(0.1)	2	0.15	4	(0.2)	4	0.25
Unlikely	13	(0.7)	17	1.12	14	(0.7)	19	1.35
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	21	(1.1)	27	1.76	18	(1.0)	23	1.60
NA	0				0			
Missing	0				0			
Outcome								
Fatal	5	(0.3)	6	0.40	5	(0.3)	6	0.39
Not recovered/not resolved	9	(0.5)	9	0.67	6	(0.3)	9	0.67
Recovered/resolved with sequelae	0				0			
Recovering/resolving	2	(0.1)	2	0.14	2	(0.1)	2	0.14
Recovered/resolved	6	(0.3)	10	0.56	6	(0.3)	6	0.39
Unknown	0				0			
Missing	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.

7.2.55 Adverse events leading to permanent discontinuation of insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	21	(1.0)	27	1.53	19	(0.9)	24	1.48
Investigations	4	(0.2)	4	0.22	1	(0.0)	1	0.04
Weight increased	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Blood glucose fluctuation	1	(0.0)	1	0.08	0			
Glycosylated haemoglobin increased	1	(0.0)	1	0.05	0			
Skin and subcutaneous tissue disorders	4	(0.2)	4	0.28	0			
Urticaria	3	(0.1)	3	0.20	0			
Alopecia	1	(0.0)	1	0.08	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	(0.2)	5	0.26	2	(0.1)	2	0.16
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Metastases to liver	1	(0.0)	1	0.05	0			
Pancreatic neoplasm	1	(0.0)	1	0.05	0			
Lung adenocarcinoma	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Infections and infestations	2	(0.1)	2	0.16	3	(0.1)	3	0.13
COVID-19 pneumonia	1	(0.0)	1	0.08	2	(0.1)	2	0.09
Pneumonia	1	(0.0)	1	0.08	0			
COVID-19	0				1	(0.0)	1	0.04
Metabolism and nutrition disorders	2	(0.1)	2	0.09	1	(0.0)	1	0.09
Obesity	1	(0.0)	1	0.05	0			
Dehydration	1	(0.0)	1	0.04	0			
Insulin resistance	0				1	(0.0)	1	0.09
General disorders and administration site conditions	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Asthenia	1	(0.0)	1	0.04	0			
Swelling face	1	(0.0)	1	0.04	0			
Death	0				1	(0.0)	1	0.05
Renal and urinary disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Nephrotic syndrome	1	(0.0)	1	0.08	0			
Hydrocalyx	0				1	(0.0)	1	0.08
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Acute respiratory failure	1	(0.0)	1	0.08	0			
Respiratory failure	0				1	(0.0)	1	0.04

%: 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 leading to permanent discontinuation of insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Cardiac disorders	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Acute myocardial infarction	1	(0.0)	1	0.04	0			
Cardiac failure acute	0				1	(0.0)	1	0.04
Angina pectoris	0				1	(0.0)	1	0.05
Gastrointestinal disorders	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Lip swelling	1	(0.0)	1	0.04	0			
Upper gastrointestinal haemorrhage	0				1	(0.0)	1	0.08
Injury, poisoning and procedural complications	1	(0.0)	3	0.13	2	(0.1)	2	0.09
Hip fracture	1	(0.0)	1	0.04	0			
Road traffic accident	1	(0.0)	1	0.04	0			
Upper limb fracture	1	(0.0)	1	0.04	0			
Fall	0				1	(0.0)	1	0.04
Rib fracture	0				1	(0.0)	1	0.05
Nervous system disorders	1	(0.0)	1	0.04	4	(0.2)	5	0.33
Amnesia	1	(0.0)	1	0.04	0			
Dizziness	0				1	(0.0)	1	0.04
Loss of consciousness	0				1	(0.0)	1	0.04
Cognitive disorder	0				1	(0.0)	1	0.08
Diabetic neuropathy	0				1	(0.0)	1	0.08
Thrombotic stroke	0				1	(0.0)	1	0.08
Hepatobiliary disorders	0				1	(0.0)	1	0.08
Liver disorder	0				1	(0.0)	1	0.08
Psychiatric disorders	0				1	(0.0)	1	0.05
Mood swings	0				1	(0.0)	1	0.05
Musculoskeletal and connective tissue disorders	0				1	(0.0)	1	0.08
Flank pain	0				1	(0.0)	1	0.08
Immune system disorders	0				1	(0.0)	1	0.08
Anaphylactic reaction	0				1	(0.0)	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.

7.2.56 Adverse events leading to permanent discontinuation of insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	21	(1.1)	27	1.76	18	(1.0)	23	1.60
Investigations	4	(0.2)	4	0.25	1	(0.1)	1	0.05
Weight increased	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Blood glucose fluctuation	1	(0.1)	1	0.09	0			
Glycosylated haemoglobin increased	1	(0.1)	1	0.05	0			
Skin and subcutaneous tissue disorders	4	(0.2)	4	0.32	0			
Urticaria	3	(0.2)	3	0.23	0			
Alopecia	1	(0.1)	1	0.09	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4	(0.2)	5	0.30	2	(0.1)	2	0.18
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Metastases to liver	1	(0.1)	1	0.05	0			
Pancreatic neoplasm	1	(0.1)	1	0.05	0			
Lung adenocarcinoma	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Infections and infestations	2	(0.1)	2	0.19	3	(0.2)	3	0.15
COVID-19 pneumonia	1	(0.1)	1	0.09	2	(0.1)	2	0.10
Pneumonia	1	(0.1)	1	0.09	0			
COVID-19	0				1	(0.1)	1	0.05
Metabolism and nutrition disorders	2	(0.1)	2	0.11	0			
Obesity	1	(0.1)	1	0.05	0			
Dehydration	1	(0.1)	1	0.05	0			
General disorders and administration site conditions	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Asthenia	1	(0.1)	1	0.05	0			
Swelling face	1	(0.1)	1	0.05	0			
Death	0				1	(0.1)	1	0.05
Renal and urinary disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Nephrotic syndrome	1	(0.1)	1	0.09	0			
Hydrocalyx	0				1	(0.1)	1	0.09
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Acute respiratory failure	1	(0.1)	1	0.09	0			
Respiratory failure	0				1	(0.1)	1	0.05
Cardiac disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Acute myocardial infarction	1	(0.1)	1	0.05	0			
Cardiac failure acute	0				1	(0.1)	1	0.05
Angina pectoris	0				1	(0.1)	1	0.05

%: 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 leading to permanent discontinuation of insulin icodec or daily basal insulin by system organ class and preferred term - on-treatment/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 disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Lip swelling	1	(0.1)	1	0.05	0			
Upper gastrointestinal haemorrhage	0				1	(0.1)	1	0.09
Injury, poisoning and procedural complications	1	(0.1)	3	0.15	2	(0.1)	2	0.11
Hip fracture	1	(0.1)	1	0.05	0			
Road traffic accident	1	(0.1)	1	0.05	0			
Upper limb fracture	1	(0.1)	1	0.05	0			
Fall	0				1	(0.1)	1	0.05
Rib fracture	0				1	(0.1)	1	0.05
Nervous system disorders	1	(0.1)	1	0.05	4	(0.2)	5	0.38
Amnesia	1	(0.1)	1	0.05	0			
Dizziness	0				1	(0.1)	1	0.05
Loss of consciousness	0				1	(0.1)	1	0.05
Cognitive disorder	0				1	(0.1)	1	0.09
Diabetic neuropathy	0				1	(0.1)	1	0.09
Thrombotic stroke	0				1	(0.1)	1	0.09
Hepatobiliary disorders	0				1	(0.1)	1	0.09
Liver disorder	0				1	(0.1)	1	0.09
Psychiatric disorders	0				1	(0.1)	1	0.05
Mood swings	0				1	(0.1)	1	0.05
Musculoskeletal and connective tissue disorders	0				1	(0.1)	1	0.09
Flank pain	0				1	(0.1)	1	0.09
Immune system disorders	0				1	(0.1)	1	0.09
Anaphylactic reaction	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.

7.2.57 Adverse events leading to temporary discontinuation of insulin icodec or daily basal insulin - on- treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	32	(1.5)	50	3.05	51	(2.4)	85	4.61
Serious								
Yes	23	(1.1)	28	1.86	39	(1.8)	62	3.31
No	12	(0.6)	22	1.19	17	(0.8)	23	1.30
Missing	0				0			
Severity								
Severe	18	(0.8)	20	1.33	27	(1.2)	44	2.36
Moderate	12	(0.6)	18	0.96	18	(0.8)	24	1.34
Mild	9	(0.4)	12	0.76	13	(0.6)	17	0.91
Missing	0				0			
Related to basal insulin								
Probable	3	(0.1)	3	0.24	0			
Possible	5	(0.2)	6	0.35	8	(0.4)	10	0.64
Unlikely	25	(1.2)	41	2.46	45	(2.1)	75	3.97
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	32	(1.5)	50	3.05	51	(2.4)	85	4.61
NA	0				0			
Missing	0				0			
Outcome								
Fatal	2	(0.1)	2	0.12	1	(0.0)	1	0.04
Not recovered/not resolved	3	(0.1)	7	0.34	10	(0.5)	14	0.64
Recovered/resolved with sequelae	3	(0.1)	3	0.17	4	(0.2)	5	0.33
Recovering/resolving	1	(0.0)	1	0.08	2	(0.1)	2	0.16
Recovered/resolved	26	(1.2)	36	2.29	44	(2.0)	63	3.44
Unknown	1	(0.0)	1	0.04	0			
Missing	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.

7.2.58 Adverse events leading to temporary discontinuation of insulin icodec or daily basal insulin - on- treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	29	(1.5)	47	3.20	49	(2.6)	83	5.11
Serious								
Yes	22	(1.2)	27	2.04	38	(2.0)	61	3.71
No	10	(0.5)	20	1.15	16	(0.9)	22	1.40
Missing	0				0			
Severity								
Severe	17	(0.9)	19	1.43	26	(1.4)	43	2.61
Moderate	11	(0.6)	17	1.00	17	(0.9)	23	1.44
Mild	8	(0.4)	11	0.77	13	(0.7)	17	1.05
Missing	0				0			
Related to basal insulin								
Probable	1	(0.1)	1	0.05	0			
Possible	4	(0.2)	5	0.30	7	(0.4)	9	0.63
Unlikely	25	(1.3)	41	2.85	44	(2.3)	74	4.47
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	29	(1.5)	47	3.20	49	(2.6)	83	5.11
NA	0				0			
Missing	0				0			
Outcome								
Fatal	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Not recovered/not resolved	3	(0.2)	7	0.40	10	(0.5)	14	0.74
Recovered/resolved with sequelae	3	(0.2)	3	0.20	4	(0.2)	5	0.38
Recovering/resolving	1	(0.1)	1	0.09	2	(0.1)	2	0.18
Recovered/resolved	23	(1.2)	33	2.32	42	(2.2)	61	3.75
Unknown	1	(0.1)	1	0.05	0			
Missing	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.

7.2.59 Adverse events leading to dose reduction of insulin icodec or daily basal insulin - on-treatment/ main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	35	(1.6)	66	4.57	40	(1.8)	66	4.03
Serious								
Yes	5	(0.2)	14	1.19	2	(0.1)	2	0.17
No	31	(1.4)	52	3.38	38	(1.8)	64	3.86
Missing	0				0			
Severity								
Severe	5	(0.2)	10	0.87	1	(0.0)	1	0.08
Moderate	3	(0.1)	10	0.66	7	(0.3)	9	0.62
Mild	29	(1.3)	46	3.04	34	(1.6)	56	3.33
Missing	0				0			
Related to basal insulin								
Probable	12	(0.6)	21	1.38	17	(0.8)	31	1.70
Possible	12	(0.6)	14	0.98	10	(0.5)	16	1.01
Unlikely	15	(0.7)	31	2.22	17	(0.8)	19	1.32
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	35	(1.6)	66	4.57	40	(1.8)	66	4.03
NA	0				0			
Missing	0				0			
Outcome								
Fatal	1	(0.0)	3	0.24	0			
Not recovered/not resolved	4	(0.2)	5	0.23	5	(0.2)	5	0.36
Recovered/resolved with sequelae	0				0			
Recovering/resolving	4	(0.2)	15	1.17	1	(0.0)	1	0.08
Recovered/resolved	28	(1.3)	43	2.94	35	(1.6)	60	3.59
Unknown	0				0			
Missing	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.

7.2.60 Adverse events leading to dose reduction of insulin icodec or daily basal insulin - on-treatment/ 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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	25	(1.3)	53	3.87	36	(1.9)	61	4.12
Serious								
Yes	1	(0.1)	9	0.83	1	(0.1)	1	0.09
No	25	(1.3)	44	3.04	35	(1.9)	60	4.03
Missing	0				0			
Severity								
Severe	1	(0.1)	5	0.46	1	(0.1)	1	0.09
Moderate	3	(0.2)	10	0.76	7	(0.4)	9	0.72
Mild	23	(1.2)	38	2.64	30	(1.6)	51	3.31
Missing	0				0			
Related to basal insulin								
Probable	6	(0.3)	13	0.73	17	(0.9)	31	1.97
Possible	10	(0.5)	12	0.91	8	(0.4)	14	0.95
Unlikely	12	(0.6)	28	2.23	14	(0.7)	16	1.20
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	25	(1.3)	53	3.87	36	(1.9)	61	4.12
NA	0				0			
Missing	0				0			
Outcome								
Fatal	1	(0.1)	3	0.28	0			
Not recovered/not resolved	4	(0.2)	5	0.26	3	(0.2)	3	0.20
Recovered/resolved with sequelae	0				0			
Recovering/resolving	4	(0.2)	15	1.35	1	(0.1)	1	0.09
Recovered/resolved	18	(1.0)	30	1.98	33	(1.8)	57	3.83
Unknown	0				0			
Missing	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.

7.2.61 Adverse events leading to dose increase of insulin icodec or daily basal insulin - on-treatment/ main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	33	(1.5)	54	3.06	36	(1.7)	41	2.64
Serious								
Yes	1	(0.0)	1	0.08	2	(0.1)	3	0.17
No	32	(1.5)	53	2.98	34	(1.6)	38	2.47
Missing	0				0			
Severity								
Severe	1	(0.0)	1	0.08	0			
Moderate	8	(0.4)	9	0.56	15	(0.7)	16	1.03
Mild	27	(1.2)	44	2.41	22	(1.0)	25	1.61
Missing	0				0			
Related to basal insulin								
Probable	4	(0.2)	4	0.22	4	(0.2)	4	0.25
Possible	1	(0.0)	3	0.23	2	(0.1)	2	0.12
Unlikely	30	(1.4)	47	2.61	30	(1.4)	35	2.27
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	33	(1.5)	54	3.06	36	(1.7)	41	2.64
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	5	(0.2)	11	0.51	8	(0.4)	8	0.58
Recovered/resolved with sequelae	0				1	(0.0)	1	0.04
Recovering/resolving	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Recovered/resolved	31	(1.4)	42	2.47	26	(1.2)	31	1.97
Unknown	0				0			
Missing	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.

7.2.62 Adverse events leading to dose increase of insulin icodec or daily basal insulin - on-treatment/ 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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	30	(1.6)	51	3.20	30	(1.6)	34	2.30
Serious								
Yes	1	(0.1)	1	0.09	2	(0.1)	3	0.20
No	29	(1.5)	50	3.11	28	(1.5)	31	2.10
Missing	0				0			
Severity								
Severe	1	(0.1)	1	0.09	0			
Moderate	7	(0.4)	8	0.54	13	(0.7)	14	0.97
Mild	25	(1.3)	42	2.57	17	(0.9)	20	1.33
Missing	0				0			
Related to basal insulin								
Probable	4	(0.2)	4	0.25	4	(0.2)	4	0.29
Possible	1	(0.1)	3	0.27	2	(0.1)	2	0.14
Unlikely	27	(1.4)	44	2.68	24	(1.3)	28	1.86
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	30	(1.6)	51	3.20	30	(1.6)	34	2.30
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	5	(0.3)	11	0.59	7	(0.4)	7	0.57
Recovered/resolved with sequelae	0				1	(0.1)	1	0.05
Recovering/resolving	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Recovered/resolved	28	(1.5)	39	2.52	21	(1.1)	25	1.63
Unknown	0				0			
Missing	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.

インスリン イコデク（遺伝子組換え）

2.7.4.7. 付録
3. 注目すべき安全性領域（イベント判定委員会が評価した事象を含む）

ノボ ノルディスク ファーマ株式会社

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7.3 Safety focus areas

7.3.1 All events sent to the event adjudication committee - summary - safety analysis set - phase 3a pool

	Insulin icodec			Daily basal insulin			Total		
	N	(%)	E	N	(%)	E	N	(%)	E
Number of subjects	2170			2170			4340		
Events submitted for adjudication	61	(2.8)	86	54	(2.5)	77	115	(2.6)	163
Acute coronary syndrome	27	(1.2)	32	24	(1.1)	27	51	(1.2)	59
Cerebrovascular event	15	(0.7)	21	19	(0.9)	23	34	(0.8)	44
Heart failure	16	(0.7)	19	10	(0.5)	14	26	(0.6)	33
Death	14	(0.6)	14	13	(0.6)	13	27	(0.6)	27

%: Percentage of subjects with one or more events, E: Number of events, N: Number of subjects with one or more events. 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): NA; criteria: POOLGR2N == 2 & SAFFL == "Y"
adadj.xpt; variable(s): ZAOBJ; criteria: POOLGR2N == 2 & SAFFL == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:57 - tadjsum/tadjeacsump3asas.txt

7.3.2 All events sent to the event adjudication committee - summary - safety analysis set - T2D pool

	Insulin icodec			Daily basal insulin			Total		
	N	(%)	E	N	(%)	E	N	(%)	E
Number of subjects	1880			1878			3758		
Events submitted for adjudication	60	(3.2)	84	52	(2.8)	74	112	(3.0)	158
Acute coronary syndrome	27	(1.4)	32	23	(1.2)	25	50	(1.3)	57
Cerebrovascular event	14	(0.7)	20	19	(1.0)	23	33	(0.9)	43
Heart failure	16	(0.9)	19	9	(0.5)	13	25	(0.7)	32
Death	13	(0.7)	13	13	(0.7)	13	26	(0.7)	26

%: Percentage of subjects with one or more events, E: Number of events, N: Number of subjects with one or more events, Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

adsl.xpt; variable(s): NA; criteria: POOLGR1N == 1 & SAFFL == "Y"
adadj.xpt; variable(s): ZAOBJ; criteria: POOLGR1N == 1 & SAFFL == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:58:59 - tadjsum/tadjeacsumt2dsas.txt

7.3.3 EAC determined cause of death - on-treatment/main-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	2170				2170			
PYE (years)	1681.2				1680.6			
Fatal events	9	(0.4)	9	0.66	11	(0.5)	11	0.60
Cardiovascular death	2	(0.1)	2	0.13	6	(0.3)	6	0.34
Acute myocardial infarction	1	(0.0)	1	0.05	2	(0.1)	2	0.12
Sudden cardiac death	0				2	(0.1)	2	0.09
Heart failure	0				0			
Stroke	0				1	(0.0)	1	0.08
Cardiovascular procedures	0				1	(0.0)	1	0.05
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	1	(0.0)	1	0.08	0			
Non-cardiovascular death	5	(0.2)	5	0.41	3	(0.1)	3	0.17
Pulmonary	0				1	(0.0)	1	0.04
Renal	0				0			
Gastrointestinal	0				1	(0.0)	1	0.08
Hepatobiliary	0				0			
Pancreatic	0				0			
Infection (includes sepsis)	3	(0.1)	3	0.24	0			
Inflammatory/immune (including autoimmune)	0				0			
Hemorrhage that is neither CV bleeding or a stroke	0				0			
Non-CV procedure or surgery	0				0			
Trauma	1	(0.0)	1	0.09	0			
Suicide	0				0			
Non-prescription drug reaction or overdose	0				0			
Prescription drug reaction or overdose (may include anaphylaxis)	0				0			
Neurological (non-CV)	0				0			
Malignancy	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Hypoglycaemia	0				0			
Other non-cardiovascular causes	0				0			
Undetermined cause of death	2	(0.1)	2	0.12	2	(0.1)	2	0.09

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of 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/main-on-treatment status is defined based on the onset date as decided by the EAC. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.3.4 EAC determined cause of death - on-treatment/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	1880				1878			
PYE (years)	1538.9				1536.5			
Fatal events	8	(0.4)	8	0.65	11	(0.6)	11	0.69
Cardiovascular death	2	(0.1)	2	0.15	6	(0.3)	6	0.39
Acute myocardial infarction	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Sudden cardiac death	0				2	(0.1)	2	0.11
Heart failure	0				0			
Stroke	0				1	(0.1)	1	0.09
Cardiovascular procedures	0				1	(0.1)	1	0.05
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	1	(0.1)	1	0.09	0			
Non-cardiovascular death	4	(0.2)	4	0.36	3	(0.2)	3	0.20
Pulmonary	0				1	(0.1)	1	0.05
Renal	0				0			
Gastrointestinal	0				1	(0.1)	1	0.09
Hepatobiliary	0				0			
Pancreatic	0				0			
Infection (includes sepsis)	3	(0.2)	3	0.27	0			
Inflammatory/immune (including autoimmune)	0				0			
Hemorrhage that is neither CV bleeding or a stroke	0				0			
Non-CV procedure or surgery	0				0			
Trauma	0				0			
Suicide	0				0			
Non-prescription drug reaction or overdose	0				0			
Prescription drug reaction or overdose (may include anaphylaxis)	0				0			
Neurological (non-CV)	0				0			
Malignancy	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Hypoglycaemia	0				0			
Other non-cardiovascular causes	0				0			
Undetermined cause of death	2	(0.1)	2	0.14	2	(0.1)	2	0.10

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of 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/main-on-treatment status is defined based on the onset date as decided by the EAC. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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.

7.3.5 EAC determined cause of death - in-trial - 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	2170				2170			
PYO (years)	1707.1				1702.1			
Fatal events	12	(0.6)	12	0.78	13	(0.6)	13	0.71
Cardiovascular death	2	(0.1)	2	0.13	6	(0.3)	6	0.34
Acute myocardial infarction	1	(0.0)	1	0.05	2	(0.1)	2	0.12
Sudden cardiac death	0				2	(0.1)	2	0.09
Heart failure	0				0			
Stroke	0				1	(0.0)	1	0.08
Cardiovascular procedures	0				1	(0.0)	1	0.05
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	1	(0.0)	1	0.08	0			
Non-cardiovascular death	7	(0.3)	7	0.49	5	(0.2)	5	0.29
Pulmonary	0				2	(0.1)	2	0.09
Renal	0				0			
Gastrointestinal	0				1	(0.0)	1	0.08
Hepatobiliary	0				0			
Pancreatic	0				0			
Infection (includes sepsis)	4	(0.2)	4	0.28	0			
Inflammatory/immune (including autoimmune)	0				0			
Hemorrhage that is neither CV bleeding or a stroke	0				0			
Non-CV procedure or surgery	0				0			
Trauma	1	(0.0)	1	0.09	0			
Suicide	0				0			
Non-prescription drug reaction or overdose	0				0			
Prescription drug reaction or overdose (may include anaphylaxis)	0				0			
Neurological (non-CV)	0				0			
Malignancy	2	(0.1)	2	0.12	2	(0.1)	2	0.12
Hypoglycaemia	0				0			
Other non-cardiovascular causes	0				0			
Undetermined cause of death	3	(0.1)	3	0.16	2	(0.1)	2	0.09

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.3.6 EAC determined cause of death - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.9				1557.5			
Fatal events	11	(0.6)	11	0.80	13	(0.7)	13	0.82
Cardiovascular death	2	(0.1)	2	0.14	6	(0.3)	6	0.39
Acute myocardial infarction	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Sudden cardiac death	0				2	(0.1)	2	0.10
Heart failure	0				0			
Stroke	0				1	(0.1)	1	0.09
Cardiovascular procedures	0				1	(0.1)	1	0.05
Cardiovascular hemorrhage	0				0			
Other cardiovascular causes	1	(0.1)	1	0.09	0			
Non-cardiovascular death	6	(0.3)	6	0.46	5	(0.3)	5	0.33
Pulmonary	0				2	(0.1)	2	0.10
Renal	0				0			
Gastrointestinal	0				1	(0.1)	1	0.09
Hepatobiliary	0				0			
Pancreatic	0				0			
Infection (includes sepsis)	4	(0.2)	4	0.32	0			
Inflammatory/immune (including autoimmune)	0				0			
Hemorrhage that is neither CV bleeding or a stroke	0				0			
Non-CV procedure or surgery	0				0			
Trauma	0				0			
Suicide	0				0			
Non-prescription drug reaction or overdose	0				0			
Prescription drug reaction or overdose (may include anaphylaxis)	0				0			
Neurological (non-CV)	0				0			
Malignancy	2	(0.1)	2	0.14	2	(0.1)	2	0.14
Hypoglycaemia	0				0			
Other non-cardiovascular causes	0				0			
Undetermined cause of death	3	(0.2)	3	0.19	2	(0.1)	2	0.10

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.3.7 EAC confirmed cardiovascular events - on-treatment/main-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	2170				2170			
PYE (years)	1681.2				1680.6			
Acute coronary syndrome	18	(0.8)	19	1.07	13	(0.6)	14	0.74
Acute myocardial infarction	17	(0.8)	18	1.02	12	(0.6)	13	0.70
STEMI	7	(0.3)	7	0.36	7	(0.3)	7	0.42
NSTEMI	9	(0.4)	10	0.62	5	(0.2)	6	0.28
Undetermined	1	(0.0)	1	0.05	0			
Hospitalisation for unstable angina pectoris	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Cerebrovascular event	4	(0.2)	4	0.28	11	(0.5)	11	0.60
Stroke	4	(0.2)	4	0.28	11	(0.5)	11	0.60
Ischaemic stroke	3	(0.1)	3	0.23	11	(0.5)	11	0.60
Hemorrhagic stroke	1	(0.0)	1	0.05	0			
Undetermined stroke	0				0			
Heart failure	5	(0.2)	6	0.27	3	(0.1)	4	0.29
Heart failure hospitalization	5	(0.2)	6	0.27	3	(0.1)	3	0.21
Urgent heart failure visit	0				1	(0.0)	1	0.08
CV death	2	(0.1)	2	0.13	6	(0.3)	6	0.34
Undetermined cause of death	2	(0.1)	2	0.12	2	(0.1)	2	0.09

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment/main-on-treatment status is defined based on the onset date as decided by the EAC. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.3.8 EAC confirmed cardiovascular events - on-treatment/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	1880				1878			
PYE (years)	1538.9				1536.5			
Acute coronary syndrome	18	(1.0)	19	1.24	13	(0.7)	14	0.86
Acute myocardial infarction	17	(0.9)	18	1.18	12	(0.6)	13	0.80
STEMI	7	(0.4)	7	0.41	7	(0.4)	7	0.49
NSTEMI	9	(0.5)	10	0.72	5	(0.3)	6	0.32
Undetermined	1	(0.1)	1	0.05	0			
Hospitalisation for unstable angina pectoris	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Cerebrovascular event	4	(0.2)	4	0.33	11	(0.6)	11	0.70
Stroke	4	(0.2)	4	0.33	11	(0.6)	11	0.70
Ischaemic stroke	3	(0.2)	3	0.27	11	(0.6)	11	0.70
Hemorrhagic stroke	1	(0.1)	1	0.05	0			
Undetermined stroke	0				0			
Heart failure	5	(0.3)	6	0.31	3	(0.2)	4	0.33
Heart failure hospitalization	5	(0.3)	6	0.31	3	(0.2)	3	0.24
Urgent heart failure visit	0				1	(0.1)	1	0.09
CV death	2	(0.1)	2	0.15	6	(0.3)	6	0.39
Undetermined cause of death	2	(0.1)	2	0.14	2	(0.1)	2	0.10

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of adverse events per 100 PYE), STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. On-treatment/main-on-treatment status is defined based on the onset date as decided by the EAC. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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.

7.3.9 EAC confirmed cardiovascular events - in-trial - 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	2170				2170			
PYO (years)	1707.1				1702.1			
Acute coronary syndrome	18	(0.8)	19	1.05	13	(0.6)	14	0.73
Acute myocardial infarction	17	(0.8)	18	1.01	12	(0.6)	13	0.69
STEMI	7	(0.3)	7	0.35	7	(0.3)	7	0.41
NSTEMI	9	(0.4)	10	0.61	5	(0.2)	6	0.27
Undetermined	1	(0.0)	1	0.05	0			
Hospitalisation for unstable angina pectoris	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Cerebrovascular event	4	(0.2)	4	0.28	11	(0.5)	11	0.59
Stroke	4	(0.2)	4	0.28	11	(0.5)	11	0.59
Ischaemic stroke	3	(0.1)	3	0.23	11	(0.5)	11	0.59
Hemorrhagic stroke	1	(0.0)	1	0.05	0			
Undetermined stroke	0				0			
Heart failure	5	(0.2)	6	0.27	3	(0.1)	4	0.28
Heart failure hospitalization	5	(0.2)	6	0.27	3	(0.1)	3	0.20
Urgent heart failure visit	0				1	(0.0)	1	0.08
CV death	2	(0.1)	2	0.13	6	(0.3)	6	0.34
Undetermined cause of death	3	(0.1)	3	0.16	2	(0.1)	2	0.09

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6.

7.3.10 EAC confirmed cardiovascular events - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.9				1557.5			
Acute coronary syndrome	18	(1.0)	19	1.22	13	(0.7)	14	0.84
Acute myocardial infarction	17	(0.9)	18	1.16	12	(0.6)	13	0.79
STEMI	7	(0.4)	7	0.41	7	(0.4)	7	0.48
NSTEMI	9	(0.5)	10	0.70	5	(0.3)	6	0.32
Undetermined	1	(0.1)	1	0.05	0			
Hospitalisation for unstable angina pectoris	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Cerebrovascular event	4	(0.2)	4	0.32	11	(0.6)	11	0.69
Stroke	4	(0.2)	4	0.32	11	(0.6)	11	0.69
Ischaemic stroke	3	(0.2)	3	0.27	11	(0.6)	11	0.69
Hemorrhagic stroke	1	(0.1)	1	0.05	0			
Undetermined stroke	0				0			
Heart failure	5	(0.3)	6	0.31	3	(0.2)	4	0.33
Heart failure hospitalization	5	(0.3)	6	0.31	3	(0.2)	3	0.24
Urgent heart failure visit	0				1	(0.1)	1	0.09
CV death	2	(0.1)	2	0.14	6	(0.3)	6	0.39
Undetermined cause of death	3	(0.2)	3	0.19	2	(0.1)	2	0.10

%: Percentage of subjects with one or more events, CV: Cardiovascular, E: Number of adverse events, EAC: Event adjudication committee, N: Number of subjects with one or more events, NSTEMI: Non-ST-segment elevation myocardial infarction, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), STEMI: ST-segment elevation myocardial infarction. Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial status is defined based on the onset date as decided by the EAC. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes.

7.3.11 Hyperglycaemia incl. diabetic ketoacidosis (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	10	(0.5)	11	0.66	21	(1.0)	22	1.38
Serious								
Yes	0				3	(0.1)	3	0.25
No	10	(0.5)	11	0.66	18	(0.8)	19	1.12
Missing	0				0			
Severity								
Severe	0				1	(0.0)	1	0.08
Moderate	3	(0.1)	3	0.20	13	(0.6)	13	0.85
Mild	7	(0.3)	8	0.46	8	(0.4)	8	0.45
Missing	0				0			
Related to basal insulin								
Probable	1	(0.0)	1	0.04	3	(0.1)	3	0.20
Possible	0				4	(0.2)	4	0.29
Unlikely	8	(0.4)	9	0.54	14	(0.6)	15	0.89
Missing	1	(0.0)	1	0.08	0			
Related to technical complaint for basal insulin								
Yes	1	(0.0)	1	0.08	1	(0.0)	1	0.08
No	9	(0.4)	9	0.51	20	(0.9)	21	1.30
NA	0				0			
Missing	1	(0.0)	1	0.08	0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	3	(0.1)	3	0.17	5	(0.2)	6	0.35
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Recovered/resolved	7	(0.3)	7	0.41	15	(0.7)	15	0.95
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.12 Hyperglycaemia incl. diabetic ketoacidosis (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	10	(0.5)	11	0.76	19	(1.0)	20	1.38
Serious								
Yes	0				2	(0.1)	2	0.18
No	10	(0.5)	11	0.76	17	(0.9)	18	1.19
Missing	0				0			
Severity								
Severe	0				1	(0.1)	1	0.09
Moderate	3	(0.2)	3	0.23	12	(0.6)	12	0.87
Mild	7	(0.4)	8	0.53	7	(0.4)	7	0.41
Missing	0				0			
Related to basal insulin								
Probable	1	(0.1)	1	0.05	3	(0.2)	3	0.24
Possible	0				4	(0.2)	4	0.33
Unlikely	8	(0.4)	9	0.62	12	(0.6)	13	0.81
Missing	1	(0.1)	1	0.09	0			
Related to technical complaint for basal insulin								
Yes	1	(0.1)	1	0.09	1	(0.1)	1	0.09
No	9	(0.5)	9	0.58	18	(1.0)	19	1.28
NA	0				0			
Missing	1	(0.1)	1	0.09	0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	3	(0.2)	3	0.20	4	(0.2)	5	0.30
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Recovered/resolved	7	(0.4)	7	0.48	14	(0.7)	14	0.99
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.13 Hyperglycaemia incl. diabetic ketoacidosis (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	10	(0.5)	11	0.66	21	(1.0)	22	1.38
Metabolism and nutrition disorders	9	(0.4)	10	0.62	17	(0.8)	17	1.10
Hyperglycaemia	6	(0.3)	7	0.48	14	(0.6)	14	0.92
Diabetes mellitus	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Diabetes mellitus inadequate control	1	(0.0)	1	0.04	0			
Insulin resistance	0				2	(0.1)	2	0.14
Investigations	1	(0.0)	1	0.05	4	(0.2)	5	0.27
Glycosylated haemoglobin increased	1	(0.0)	1	0.05	2	(0.1)	3	0.13
Blood glucose increased	0				2	(0.1)	2	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.14 Hyperglycaemia incl. diabetic ketoacidosis (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	10	(0.5)	11	0.76	19	(1.0)	20	1.38
Metabolism and nutrition disorders	9	(0.5)	10	0.71	16	(0.9)	16	1.17
Hyperglycaemia	6	(0.3)	7	0.56	14	(0.7)	14	1.06
Diabetes mellitus	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Diabetes mellitus inadequate control	1	(0.1)	1	0.05	0			
Insulin resistance	0				1	(0.1)	1	0.05
Investigations	1	(0.1)	1	0.05	3	(0.2)	4	0.21
Glycosylated haemoglobin increased	1	(0.1)	1	0.05	2	(0.1)	3	0.15
Blood glucose increased	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.15 Hyperglycaemia incl. diabetic ketoacidosis (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	0	(0.0)	0	0.00	3	(0.1)	3	0.25
Metabolism and nutrition disorders	0				2	(0.1)	2	0.16
Hyperglycaemia	0				2	(0.1)	2	0.16
Investigations	0				1	(0.0)	1	0.09
Blood glucose increased	0				1	(0.0)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ07NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:59:59 - taesocpt/taessocpthyperglycsumontp3asas.txt

7.3.16 Hyperglycaemia incl. diabetic ketoacidosis (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	0	(0.0)	0	0.00	2	(0.1)	2	0.18
Metabolism and nutrition disorders	0				2	(0.1)	2	0.18
Hyperglycaemia	0				2	(0.1)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ07NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:01 - taesocpt/taessocpthyperglycsumontt2dsas.txt

7.3.17 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	13	(0.6)	13	0.86	21	(1.0)	21	1.35
Serious								
Yes	1	(0.0)	1	0.08	1	(0.0)	1	0.08
No	12	(0.6)	12	0.78	20	(0.9)	20	1.27
Missing	0				0			
Severity								
Severe	1	(0.0)	1	0.08	0			
Moderate	4	(0.2)	4	0.25	5	(0.2)	5	0.30
Mild	8	(0.4)	8	0.53	16	(0.7)	16	1.06
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	13	(0.6)	13	0.86	21	(1.0)	21	1.35
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	13	(0.6)	13	0.86	21	(1.0)	21	1.35
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	8	(0.4)	8	0.52	15	(0.7)	15	1.01
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				2	(0.1)	2	0.16
Recovered/resolved	5	(0.2)	5	0.35	4	(0.2)	4	0.18
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.18 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	11	(0.6)	11	0.78	19	(1.0)	19	1.35
Serious								
Yes	1	(0.1)	1	0.09	1	(0.1)	1	0.09
No	10	(0.5)	10	0.68	18	(1.0)	18	1.26
Missing	0				0			
Severity								
Severe	1	(0.1)	1	0.09	0			
Moderate	4	(0.2)	4	0.29	5	(0.3)	5	0.34
Mild	6	(0.3)	6	0.40	14	(0.7)	14	1.01
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	11	(0.6)	11	0.78	19	(1.0)	19	1.35
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	11	(0.6)	11	0.78	19	(1.0)	19	1.35
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	7	(0.4)	7	0.49	13	(0.7)	13	0.96
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				2	(0.1)	2	0.18
Recovered/resolved	4	(0.2)	4	0.29	4	(0.2)	4	0.21
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.19 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/ main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	13	(0.6)	13	0.86	21	(1.0)	21	1.35
Nervous system disorders	6	(0.3)	6	0.42	12	(0.6)	12	0.75
Diabetic neuropathy	6	(0.3)	6	0.42	12	(0.6)	12	0.75
Renal and urinary disorders	5	(0.2)	5	0.31	5	(0.2)	5	0.39
Diabetic nephropathy	3	(0.1)	3	0.17	4	(0.2)	4	0.34
Microalbuminuria	2	(0.1)	2	0.14	1	(0.0)	1	0.04
Infections and infestations	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Diabetic foot infection	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Diabetic foot	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Musculoskeletal and connective tissue disorders	0				1	(0.0)	1	0.08
Neuropathic arthropathy	0				1	(0.0)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.20 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/ 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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	11	(0.6)	11	0.78	19	(1.0)	19	1.35
Nervous system disorders	5	(0.3)	5	0.38	12	(0.6)	12	0.87
Diabetic neuropathy	5	(0.3)	5	0.38	12	(0.6)	12	0.87
Renal and urinary disorders	4	(0.2)	4	0.25	3	(0.2)	3	0.23
Diabetic nephropathy	3	(0.2)	3	0.20	2	(0.1)	2	0.18
Microalbuminuria	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Infections and infestations	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Diabetic foot infection	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Diabetic foot	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Musculoskeletal and connective tissue disorders	0				1	(0.1)	1	0.09
Neuropathic arthropathy	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.21 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on- treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Infections and infestations	1	(0.0)	1	0.08	0			
Diabetic foot infection	1	(0.0)	1	0.08	0			
Nervous system disorders	0				1	(0.0)	1	0.08
Diabetic neuropathy	0				1	(0.0)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ14NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:08 - taesocpt/taessocptmicrovsumontp3asas.txt

7.3.22 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on- treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Infections and infestations	1	(0.1)	1	0.09	0			
Diabetic foot infection	1	(0.1)	1	0.09	0			
Nervous system disorders	0				1	(0.1)	1	0.09
Diabetic neuropathy	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ14NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:11 - taesocpt/taessocptmicrovsumontt2dsas.txt

7.3.23 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	13	(0.6)	13	0.85	21	(1.0)	21	1.34
Serious								
Yes	1	(0.0)	1	0.08	1	(0.0)	1	0.08
No	12	(0.6)	12	0.77	20	(0.9)	20	1.26
Missing	0				0			
Severity								
Severe	1	(0.0)	1	0.08	0			
Moderate	4	(0.2)	4	0.24	5	(0.2)	5	0.29
Mild	8	(0.4)	8	0.53	16	(0.7)	16	1.04
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	13	(0.6)	13	0.85	21	(1.0)	21	1.34
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	13	(0.6)	13	0.85	21	(1.0)	21	1.34
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	8	(0.4)	8	0.51	15	(0.7)	15	1.00
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				2	(0.1)	2	0.16
Recovered/resolved	5	(0.2)	5	0.34	4	(0.2)	4	0.18
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ14NAM != "" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:07:01 - taesum/taemicrovsumintp3asas.txt

7.3.24 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	11	(0.6)	11	0.77	19	(1.0)	19	1.33
Serious								
Yes	1	(0.1)	1	0.09	1	(0.1)	1	0.09
No	10	(0.5)	10	0.68	18	(1.0)	18	1.24
Missing	0				0			
Severity								
Severe	1	(0.1)	1	0.09	0			
Moderate	4	(0.2)	4	0.28	5	(0.3)	5	0.34
Mild	6	(0.3)	6	0.40	14	(0.7)	14	0.99
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	11	(0.6)	11	0.77	19	(1.0)	19	1.33
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	11	(0.6)	11	0.77	19	(1.0)	19	1.33
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	7	(0.4)	7	0.48	13	(0.7)	13	0.94
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				2	(0.1)	2	0.18
Recovered/resolved	4	(0.2)	4	0.29	4	(0.2)	4	0.21
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.25 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	13	(0.6)	13	0.85	21	(1.0)	21	1.34
Nervous system disorders	6	(0.3)	6	0.42	12	(0.6)	12	0.74
Diabetic neuropathy	6	(0.3)	6	0.42	12	(0.6)	12	0.74
Renal and urinary disorders	5	(0.2)	5	0.31	5	(0.2)	5	0.38
Diabetic nephropathy	3	(0.1)	3	0.17	4	(0.2)	4	0.34
Microalbuminuria	2	(0.1)	2	0.14	1	(0.0)	1	0.04
Infections and infestations	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Diabetic foot infection	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Diabetic foot	1	(0.0)	1	0.04	2	(0.1)	2	0.09
Musculoskeletal and connective tissue disorders	0				1	(0.0)	1	0.08
Neuropathic arthropathy	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ14NAM != "" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:13 - taesocpt/taesocptmicrovsumintp3asas.txt

7.3.26 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	11	(0.6)	11	0.77	19	(1.0)	19	1.33
Nervous system disorders	5	(0.3)	5	0.38	12	(0.6)	12	0.85
Diabetic neuropathy	5	(0.3)	5	0.38	12	(0.6)	12	0.85
Renal and urinary disorders	4	(0.2)	4	0.25	3	(0.2)	3	0.23
Diabetic nephropathy	3	(0.2)	3	0.20	2	(0.1)	2	0.18
Microalbuminuria	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Infections and infestations	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Diabetic foot infection	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.10
Diabetic foot	1	(0.1)	1	0.05	2	(0.1)	2	0.10
Musculoskeletal and connective tissue disorders	0				1	(0.1)	1	0.09
Neuropathic arthropathy	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ14NAM != "" & (ANL01FL) == "Y"

7.3.27 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in- trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Infections and infestations	1	(0.0)	1	0.08	0			
Diabetic foot infection	1	(0.0)	1	0.08	0			
Nervous system disorders	0				1	(0.0)	1	0.08
Diabetic neuropathy	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ14NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:18 - taesocpt/taessocptmicrovsumintp3asas.txt

7.3.28 Other microvascular diabetic complications (peripheral vascular disease and renal impairment) (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in- trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Infections and infestations	1	(0.1)	1	0.09	0			
Diabetic foot infection	1	(0.1)	1	0.09	0			
Nervous system disorders	0				1	(0.1)	1	0.09
Diabetic neuropathy	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ14NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:20 - taesocpt/taessocptmicrovsumintt2dsas.txt

7.3.29 Localised amyloidosis (predefined MedDRA search) - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ13NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:07:05 - taesum/taeamylsumontp3asas.txt

7.3.30 Localised amyloidosis (predefined MedDRA search) - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ13NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:07:07 - taesum/taeamylsumontt2dsas.txt

7.3.31 Localised amyloidosis (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ13NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:22 - taesocpt/taesocptamylsumontp3asas.txt

7.3.32 Localised amyloidosis (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ13NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:24 - taesocpt/taesocptamylsumontt2dsas.txt

7.3.33 Localised amyloidosis (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                    CQ13NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:00:26 - taesocpt/taessocptamylsumontp3asas.txt
```

7.3.34 Localised amyloidosis (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                    CQ13NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:00:28 - taesocpt/taessocptamylsumontt2dsas.txt
```

7.3.35 Localised amyloidosis (predefined MedDRA search) - in-trial - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
       adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" &
                                                  (ANELFL) == "Y" & CQ13NAM != "" & (ANL01FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                                05DEC2022:13:07:09 - taesum/taeamylsumintp3asas.txt
```

7.3.36 Localised amyloidosis (predefined MedDRA search) - in-trial - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
       adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" &
                                                  (ANELFL) == "Y" & CQ13NAM != "" & (ANL01FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                                05DEC2022:13:07:11 - taesum/taeamylsumintt2dsas.txt
```

7.3.37 Localised amyloidosis (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                                    CQ13NAM != "" & (ANL01FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:00:30 - taesocpt/taesocptamylsumintp3asas.txt
```

7.3.38 Localised amyloidosis (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                                    CQ13NAM != "" & (ANL01FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:00:31 - taesocpt/taesocptamylsumintt2dsas.txt
```

7.3.39 Localised amyloidosis (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ13NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                         05DEC2022:13:00:33 - taesocpt/taessocptamylsumintp3asas.txt
```

7.3.40 Localised amyloidosis (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ13NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                         05DEC2022:13:00:35 - taesocpt/taessocptamylsumintt2dsas.txt
```

7.3.41 Clinically meaningful peripheral oedema (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	24	(1.1)	25	1.57	14	(0.6)	15	0.87
Serious								
Yes	0				1	(0.0)	1	0.04
No	24	(1.1)	25	1.57	13	(0.6)	14	0.83
Missing	0				0			
Severity								
Severe	0				0			
Moderate	3	(0.1)	3	0.17	3	(0.1)	4	0.18
Mild	21	(1.0)	22	1.40	11	(0.5)	11	0.69
Missing	0				0			
Related to basal insulin								
Probable	1	(0.0)	1	0.08	1	(0.0)	2	0.09
Possible	2	(0.1)	2	0.09	0			
Unlikely	21	(1.0)	22	1.40	13	(0.6)	13	0.78
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	24	(1.1)	25	1.57	14	(0.6)	15	0.87
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	8	(0.4)	8	0.52	3	(0.1)	3	0.17
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	17	(0.8)	17	1.05	11	(0.5)	12	0.70
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.42 Clinically meaningful peripheral oedema (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	22	(1.2)	23	1.60	13	(0.7)	14	0.90
Serious								
Yes	0				1	(0.1)	1	0.05
No	22	(1.2)	23	1.60	12	(0.6)	13	0.85
Missing	0				0			
Severity								
Severe	0				0			
Moderate	3	(0.2)	3	0.20	3	(0.2)	4	0.21
Mild	19	(1.0)	20	1.40	10	(0.5)	10	0.69
Missing	0				0			
Related to basal insulin								
Probable	1	(0.1)	1	0.09	1	(0.1)	2	0.11
Possible	2	(0.1)	2	0.10	0			
Unlikely	19	(1.0)	20	1.40	12	(0.6)	12	0.80
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	22	(1.2)	23	1.60	13	(0.7)	14	0.90
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	6	(0.3)	6	0.39	3	(0.2)	3	0.20
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	17	(0.9)	17	1.21	10	(0.5)	11	0.70
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ09NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:07:15 - taesum/taepheoedsumontt2dsas.txt

7.3.43 Clinically meaningful peripheral oedema (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	24	(1.1)	25	1.57	14	(0.6)	15	0.87
General disorders and administration site conditions	24	(1.1)	25	1.57	14	(0.6)	15	0.87
Oedema peripheral	19	(0.9)	19	1.23	10	(0.5)	11	0.62
Peripheral swelling	5	(0.2)	6	0.34	4	(0.2)	4	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ09NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:37 - taesocpt/taesocptpheoedsumontp3asas.txt

7.3.44 Clinically meaningful peripheral oedema (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	22	(1.2)	23	1.60	13	(0.7)	14	0.90
General disorders and administration site conditions	22	(1.2)	23	1.60	13	(0.7)	14	0.90
Oedema peripheral	17	(0.9)	17	1.21	9	(0.5)	10	0.61
Peripheral swelling	5	(0.3)	6	0.39	4	(0.2)	4	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ09NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:40 - taesocpt/taesocptpheoedsumontt2dsas.txt

7.3.45 Clinically meaningful peripheral oedema (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	0	(0.0)	0	0.00	1	(0.0)	1	0.04
General disorders and administration site conditions	0				1	(0.0)	1	0.04
Peripheral swelling	0				1	(0.0)	1	0.04

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ09NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:42 - taesocpt/taessocptpheoedsumontp3asas.txt

7.3.46 Clinically meaningful peripheral oedema (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	0	(0.0)	0	0.00	1	(0.1)	1	0.05
General disorders and administration site conditions	0				1	(0.1)	1	0.05
Peripheral swelling	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ09NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:44 - taesocpt/taessocptpheoedsumontt2dsas.txt

7.3.47 Hypokalaemia (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	2	(0.1)	2	0.13	1	(0.0)	1	0.05
Serious								
Yes	0				0			
No	2	(0.1)	2	0.13	1	(0.0)	1	0.05
Missing	0				0			
Severity								
Severe	0				0			
Moderate	1	(0.0)	1	0.05	0			
Mild	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	2	(0.1)	2	0.13	1	(0.0)	1	0.05
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	2	(0.1)	2	0.13	1	(0.0)	1	0.05
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	1	(0.0)	1	0.08	0			
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries. The hypokalaemia MedDRA search captured three events fewer than the broader search erroneously applied for ONWARDS 2 clinical trial report.

7.3.48 Hypokalaemia (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Serious								
Yes	0				0			
No	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Missing	0				0			
Severity								
Severe	0				0			
Moderate	1	(0.1)	1	0.05	0			
Mild	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	2	(0.1)	2	0.15	1	(0.1)	1	0.05
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	1	(0.1)	1	0.09	0			
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries. The hypokalaemia MedDRA search captured three events fewer than the broader search erroneously applied for ONWARDS 2 clinical trial report.

7.3.49 Hypokalaemia (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	2	(0.1)	2	0.13	1	(0.0)	1	0.05
Metabolism and nutrition disorders	2	(0.1)	2	0.13	1	(0.0)	1	0.05
Hypokalaemia	2	(0.1)	2	0.13	1	(0.0)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries. The hypokalaemia MedDRA search captured three events fewer than the broader search erroneously applied for ONWARDS 2 clinical trial report.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ10NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:46 - taesocpt/taesocpthypokasumontp3asas.txt

7.3.50 Hypokalaemia (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Metabolism and nutrition disorders	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Hypokalaemia	2	(0.1)	2	0.15	1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries. The hypokalaemia MedDRA search captured three events fewer than the broader search erroneously applied for ONWARDS 2 clinical trial report.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ10NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:49 - taesocpt/taesocpthypokasumontt2dsas.txt

7.3.51 Hypokalaemia (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ10NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                            nn1436/nn1436-iss/submission_20221024_er
                                        05DEC2022:13:00:51 - taesocpt/taessocpthypokasumontp3asas.txt
```

7.3.52 Hypokalaemia (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ10NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                            nn1436/nn1436-iss/submission_20221024_er
                                        05DEC2022:13:00:53 - taesocpt/taessocpthypokasumontt2dsas.txt
```

7.3.53 Lipodystrophy (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Serious								
Yes	0				0			
No	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Missing	0				0			
Severity								
Severe	0				0			
Moderate	0				0			
Mild	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Missing	0				0			
Related to basal insulin								
Probable	1	(0.0)	1	0.05	0			
Possible	0				1	(0.0)	1	0.05
Unlikely	0				1	(0.0)	1	0.08
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	1	(0.0)	1	0.05	2	(0.1)	2	0.13
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	0				1	(0.0)	1	0.05
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.0)	1	0.05	0			
Recovered/resolved	0				1	(0.0)	1	0.08
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.54 Lipodystrophy (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Serious								
Yes	0				0			
No	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Missing	0				0			
Severity								
Severe	0				0			
Moderate	0				0			
Mild	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Missing	0				0			
Related to basal insulin								
Probable	1	(0.1)	1	0.05	0			
Possible	0				1	(0.1)	1	0.05
Unlikely	0				1	(0.1)	1	0.09
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	1	(0.1)	1	0.05	2	(0.1)	2	0.15
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	0				1	(0.1)	1	0.05
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.1)	1	0.05	0			
Recovered/resolved	0				1	(0.1)	1	0.09
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.55 Lipodystrophy (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Lipodystrophy acquired	1	(0.0)	1	0.05	0			
Lipohypertrophy	0				2	(0.1)	2	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ12NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:55 - taesocpt/taesocptliposumontp3asas.txt

7.3.56 Lipodystrophy (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Lipodystrophy acquired	1	(0.1)	1	0.05	0			
Lipohypertrophy	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ12NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:00:57 - taesocpt/taesocptliposumontt2dsas.txt

7.3.57 Lipodystrophy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

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There is no data for this output
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```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ12NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                            nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:00:59 - taesocpt/taessocptliposumontp3asas.txt
```

7.3.58 Lipodystrophy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

```
There is no data for this output
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```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ12NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                            nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:01:01 - taesocpt/taessocptliposumontt2dsas.txt
```

7.3.59 Lipodystrophy (predefined MedDRA search) - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Serious								
Yes	0				0			
No	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Missing	0				0			
Severity								
Severe	0				0			
Moderate	0				0			
Mild	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Missing	0				0			
Related to basal insulin								
Probable	1	(0.0)	1	0.05	0			
Possible	0				1	(0.0)	1	0.05
Unlikely	0				1	(0.0)	1	0.08
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	1	(0.0)	1	0.05	2	(0.1)	2	0.13
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	0				1	(0.0)	1	0.05
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.0)	1	0.05	0			
Recovered/resolved	0				1	(0.0)	1	0.08
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.60 Lipodystrophy (predefined MedDRA search) - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Serious								
Yes	0				0			
No	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Missing	0				0			
Severity								
Severe	0				0			
Moderate	0				0			
Mild	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Missing	0				0			
Related to basal insulin								
Probable	1	(0.1)	1	0.05	0			
Possible	0				1	(0.1)	1	0.05
Unlikely	0				1	(0.1)	1	0.09
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	1	(0.1)	1	0.05	2	(0.1)	2	0.14
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	0				1	(0.1)	1	0.05
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.1)	1	0.05	0			
Recovered/resolved	0				1	(0.1)	1	0.09
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.61 Lipodystrophy (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Lipodystrophy acquired	1	(0.0)	1	0.05	0			
Lipohypertrophy	0				2	(0.1)	2	0.13

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ12NAM != "" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:03 - taesocpt/taesocptliposumintp3asas.txt

7.3.62 Lipodystrophy (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Lipodystrophy acquired	1	(0.1)	1	0.05	0			
Lipohypertrophy	0				2	(0.1)	2	0.14

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ12NAM != "" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:06 - taesocpt/taesocptliposumintt2dsas.txt

7.3.63 Lipodystrophy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

```
There is no data for this output
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```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ12NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
                                                            nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:01:08 - taesocpt/taessocptliposumintp3asas.txt
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7.3.64 Lipodystrophy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

```
There is no data for this output
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```
                              adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ12NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
                                                            nn1436/nn1436-iss/submission_20221024_er
                                          05DEC2022:13:01:09 - taesocpt/taessocptliposumintt2dsas.txt
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7.3.65 Neoplasms (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	62	(2.9)	74	4.50	65	(3.0)	85	5.17
Serious								
Yes	17	(0.8)	20	1.18	22	(1.0)	26	1.45
No	49	(2.3)	54	3.33	49	(2.3)	59	3.72
Missing	0				0			
Severity								
Severe	6	(0.3)	7	0.35	13	(0.6)	17	0.94
Moderate	15	(0.7)	17	1.04	11	(0.5)	12	0.65
Mild	45	(2.1)	50	3.11	47	(2.2)	56	3.58
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	62	(2.9)	74	4.50	65	(3.0)	85	5.17
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	62	(2.9)	74	4.50	65	(3.0)	85	5.17
NA	0				0			
Missing	0				0			
Outcome								
Fatal	3	(0.1)	4	0.18	2	(0.1)	2	0.12
Not recovered/not resolved	35	(1.6)	41	2.55	44	(2.0)	55	3.44
Recovered/resolved with sequelae	0				0			
Recovering/resolving	5	(0.2)	6	0.35	5	(0.2)	5	0.34
Recovered/resolved	23	(1.1)	23	1.42	21	(1.0)	23	1.26
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.66 Neoplasms (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	54	(2.9)	66	4.33	56	(3.0)	74	4.79
Serious								
Yes	17	(0.9)	20	1.36	22	(1.2)	26	1.67
No	41	(2.2)	46	2.97	40	(2.1)	48	3.11
Missing	0				0			
Severity								
Severe	6	(0.3)	7	0.40	13	(0.7)	17	1.08
Moderate	15	(0.8)	17	1.21	11	(0.6)	12	0.75
Mild	37	(2.0)	42	2.72	38	(2.0)	45	2.96
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	54	(2.9)	66	4.33	56	(3.0)	74	4.79
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	54	(2.9)	66	4.33	56	(3.0)	74	4.79
NA	0				0			
Missing	0				0			
Outcome								
Fatal	3	(0.2)	4	0.21	2	(0.1)	2	0.14
Not recovered/not resolved	30	(1.6)	36	2.40	37	(2.0)	46	3.00
Recovered/resolved with sequelae	0				0			
Recovering/resolving	4	(0.2)	5	0.30	4	(0.2)	4	0.29
Recovered/resolved	21	(1.1)	21	1.42	20	(1.1)	22	1.35
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.67 Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - on- treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	62	(2.9)	74	4.50	65	(3.0)	85	5.17
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	35	(1.6)	43	2.59	29	(1.3)	43	2.50
Colon adenoma	3	(0.1)	3	0.20	0			
Eye naevus	3	(0.1)	4	0.26	0			
Haemangioma of liver	2	(0.1)	2	0.14	0			
Pancreatic neoplasm	2	(0.1)	2	0.13	0			
Seborrhoeic keratosis	2	(0.1)	3	0.14	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Colorectal cancer	2	(0.1)	2	0.12	0			
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Benign neoplasm of thyroid gland	1	(0.0)	1	0.09	0			
Melanocytic naevus	1	(0.0)	1	0.09	0			
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Gastric cancer	1	(0.0)	1	0.08	0			
Bladder papilloma	1	(0.0)	1	0.08	0			
Lung cancer metastatic	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Skin papilloma	1	(0.0)	1	0.08	0			
Osteoma	1	(0.0)	1	0.08	0			
Small cell lung cancer	1	(0.0)	1	0.08	0			
Acrochordon	1	(0.0)	1	0.05	0			
Basal cell carcinoma	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Neoplasm skin	1	(0.0)	1	0.05	0			
Oral fibroma	1	(0.0)	1	0.05	0			
Prostate cancer	1	(0.0)	1	0.05	0			
Salivary gland neoplasm	1	(0.0)	1	0.05	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Invasive ductal breast carcinoma	1	(0.0)	1	0.04	0			
Invasive lobular breast carcinoma	1	(0.0)	1	0.04	0			
Lipoma	1	(0.0)	1	0.04	0			
Pancreatic carcinoma	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Renal neoplasm	1	(0.0)	1	0.04	0			
Squamous cell carcinoma of skin	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Uterine leiomyoma	0				5	(0.2)	5	0.36
Benign renal neoplasm	0				2	(0.1)	2	0.14
Adrenal adenoma	0				2	(0.1)	2	0.16
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Bowen's disease	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Gastrointestinal tract adenoma	0				1	(0.0)	1	0.04
Invasive breast carcinoma	0				1	(0.0)	1	0.04
Malignant melanoma	0				1	(0.0)	1	0.04
Malignant peritoneal neoplasm	0				1	(0.0)	1	0.04
Metastases to bone marrow	0				1	(0.0)	1	0.04
Metastases to lymph nodes	0				1	(0.0)	1	0.04
Myxoma	0				1	(0.0)	1	0.04

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Prostatic adenoma	0				1	(0.0)	1	0.04
Renal hamartoma	0				1	(0.0)	1	0.04
Small intestine neuroendocrine tumour	0				1	(0.0)	1	0.08
Uterine cancer	0				1	(0.0)	1	0.08
Colon cancer	0				1	(0.0)	1	0.05
Dysplastic naevus	0				1	(0.0)	1	0.05
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Malignant melanoma in situ	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Breast cancer	0				1	(0.0)	1	0.08
Colon cancer stage II	0				1	(0.0)	1	0.08
Lymphangioma	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Gastrointestinal disorders	8	(0.4)	8	0.43	13	(0.6)	15	0.88
Large intestine polyp	4	(0.2)	4	0.21	6	(0.3)	7	0.35
Gastric polyps	2	(0.1)	2	0.13	4	(0.2)	4	0.31
Rectal polyp	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Crohn's disease	0				1	(0.0)	1	0.05
Gastric dysplasia	0				1	(0.0)	1	0.08
Renal and urinary disorders	7	(0.3)	7	0.45	5	(0.2)	5	0.31
Renal cyst	7	(0.3)	7	0.45	5	(0.2)	5	0.31
Musculoskeletal and connective tissue disorders	4	(0.2)	4	0.23	2	(0.1)	2	0.12
Synovial cyst	3	(0.1)	3	0.19	1	(0.0)	1	0.04
Bone cyst	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Reproductive system and breast disorders	4	(0.2)	4	0.22	2	(0.1)	2	0.14
Uterine polyp	2	(0.1)	2	0.09	0			
Cervical polyp	1	(0.0)	1	0.08	0			
Ovarian cyst	1	(0.0)	1	0.05	0			
Testicular cyst	0				1	(0.0)	1	0.04
Fibrocystic breast disease	0				1	(0.0)	1	0.09
Hepatobiliary disorders	2	(0.1)	2	0.17	4	(0.2)	4	0.31
Gallbladder polyp	2	(0.1)	2	0.17	3	(0.1)	3	0.27
Hepatic cyst	0				1	(0.0)	1	0.05
Investigations	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Prostatic specific antigen increased	2	(0.1)	2	0.09	0			
Carbohydrate antigen 19-9 increased	0				1	(0.0)	1	0.04
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.09	6	(0.3)	6	0.39
Dermal cyst	1	(0.0)	1	0.09	4	(0.2)	4	0.27
Actinic keratosis	0				1	(0.0)	1	0.05
Leukoplakia	0				1	(0.0)	1	0.08
Surgical and medical procedures	1	(0.0)	1	0.09	2	(0.1)	2	0.09
Skin neoplasm excision	1	(0.0)	1	0.09	1	(0.0)	1	0.04
Large intestinal polypectomy	0				1	(0.0)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Infections and infestations	1	(0.0)	1	0.08	1	(0.0)	1	0.09
Infected dermal cyst	1	(0.0)	1	0.08	0			
Infected cyst	0				1	(0.0)	1	0.09
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.05	2	(0.1)	2	0.16
Laryngeal cyst	1	(0.0)	1	0.05	0			
Paranasal cyst	0				2	(0.1)	2	0.16
General disorders and administration site conditions	0				2	(0.1)	2	0.12
Cyst	0				2	(0.1)	2	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.68 Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - on- treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	54	(2.9)	66	4.33	56	(3.0)	74	4.79
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	31	(1.6)	39	2.56	27	(1.4)	40	2.56
Colon adenoma	3	(0.2)	3	0.23	0			
Pancreatic neoplasm	2	(0.1)	2	0.15	0			
Seborrhoeic keratosis	2	(0.1)	3	0.16	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Colorectal cancer	2	(0.1)	2	0.14	0			
Eye naevus	2	(0.1)	3	0.20	0			
Metastases to liver	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Gastric cancer	1	(0.1)	1	0.09	0			
Bladder papilloma	1	(0.1)	1	0.09	0			
Lung cancer metastatic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Skin papilloma	1	(0.1)	1	0.09	0			
Osteoma	1	(0.1)	1	0.09	0			
Small cell lung cancer	1	(0.1)	1	0.09	0			
Acrochordon	1	(0.1)	1	0.05	0			
Basal cell carcinoma	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Haemangioma of liver	1	(0.1)	1	0.05	0			
Neoplasm skin	1	(0.1)	1	0.05	0			
Oral fibroma	1	(0.1)	1	0.05	0			
Prostate cancer	1	(0.1)	1	0.05	0			
Salivary gland neoplasm	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Invasive ductal breast carcinoma	1	(0.1)	1	0.05	0			
Invasive lobular breast carcinoma	1	(0.1)	1	0.05	0			
Lipoma	1	(0.1)	1	0.05	0			
Pancreatic carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Renal neoplasm	1	(0.1)	1	0.05	0			
Squamous cell carcinoma of skin	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Uterine leiomyoma	0				3	(0.2)	3	0.20
Adrenal adenoma	0				2	(0.1)	2	0.18
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Benign renal neoplasm	0				1	(0.1)	1	0.05
Bowen's disease	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Gastrointestinal tract adenoma	0				1	(0.1)	1	0.05
Invasive breast carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma	0				1	(0.1)	1	0.05
Malignant peritoneal neoplasm	0				1	(0.1)	1	0.05
Metastases to bone marrow	0				1	(0.1)	1	0.05
Metastases to lymph nodes	0				1	(0.1)	1	0.05
Myxoma	0				1	(0.1)	1	0.05
Prostatic adenoma	0				1	(0.1)	1	0.05
Renal hamartoma	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	0				1	(0.1)	1	0.09
Uterine cancer	0				1	(0.1)	1	0.09
Colon cancer	0				1	(0.1)	1	0.05
Dysplastic naevus	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma in situ	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Breast cancer	0				1	(0.1)	1	0.09
Colon cancer stage II	0				1	(0.1)	1	0.09
Lymphangioma	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Gastrointestinal disorders	8	(0.4)	8	0.50	11	(0.6)	13	0.80
Large intestine polyp	4	(0.2)	4	0.25	6	(0.3)	7	0.41
Gastric polyps	2	(0.1)	2	0.15	2	(0.1)	2	0.15
Rectal polyp	2	(0.1)	2	0.11	2	(0.1)	2	0.11
Crohn's disease	0				1	(0.1)	1	0.05
Gastric dysplasia	0				1	(0.1)	1	0.09
Renal and urinary disorders	7	(0.4)	7	0.52	4	(0.2)	4	0.25
Renal cyst	7	(0.4)	7	0.52	4	(0.2)	4	0.25
Reproductive system and breast disorders	4	(0.2)	4	0.25	1	(0.1)	1	0.05
Uterine polyp	2	(0.1)	2	0.11	0			
Cervical polyp	1	(0.1)	1	0.09	0			
Ovarian cyst	1	(0.1)	1	0.05	0			
Testicular cyst	0				1	(0.1)	1	0.05
Musculoskeletal and connective tissue disorders	3	(0.2)	3	0.16	2	(0.1)	2	0.14
Synovial cyst	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Bone cyst	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Investigations	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Prostatic specific antigen increased	2	(0.1)	2	0.10	0			
Carbohydrate antigen 19-9 increased	0				1	(0.1)	1	0.05
Hepatobiliary disorders	1	(0.1)	1	0.09	2	(0.1)	2	0.15
Gallbladder polyp	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Hepatic cyst	0				1	(0.1)	1	0.05
Infections and infestations	1	(0.1)	1	0.09	0			
Infected dermal cyst	1	(0.1)	1	0.09	0			
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.19
Laryngeal cyst	1	(0.1)	1	0.05	0			
Paranasal cyst	0				2	(0.1)	2	0.19

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	0			5	(0.3)	5 0.34
Dermal cyst	0			3	(0.2)	3 0.20
Actinic keratosis	0			1	(0.1)	1 0.05
Leukoplakia	0			1	(0.1)	1 0.09
General disorders and administration site conditions	0			2	(0.1)	2 0.14
Cyst	0			2	(0.1)	2 0.14
Surgical and medical procedures	0			2	(0.1)	2 0.11
Skin neoplasm excision	0			1	(0.1)	1 0.05
Large intestinal polypectomy	0			1	(0.1)	1 0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.69 Neoplasms (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	17	(0.8)	20	1.18	22	(1.0)	26	1.45
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	(0.7)	18	1.05	19	(0.9)	23	1.28
Pancreatic neoplasm	2	(0.1)	2	0.13	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Colorectal cancer	2	(0.1)	2	0.12	0			
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Gastric cancer	1	(0.0)	1	0.08	0			
Lung cancer metastatic	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Small cell lung cancer	1	(0.0)	1	0.08	0			
Basal cell carcinoma	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Invasive ductal breast carcinoma	1	(0.0)	1	0.04	0			
Invasive lobular breast carcinoma	1	(0.0)	1	0.04	0			
Pancreatic carcinoma	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Benign renal neoplasm	0				1	(0.0)	1	0.04
Bowen's disease	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Invasive breast carcinoma	0				1	(0.0)	1	0.04
Malignant melanoma	0				1	(0.0)	1	0.04
Uterine leiomyoma	0				1	(0.0)	1	0.04
Small intestine neuroendocrine tumour	0				1	(0.0)	1	0.08
Uterine cancer	0				1	(0.0)	1	0.08
Colon cancer	0				1	(0.0)	1	0.05
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Malignant melanoma in situ	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Colon cancer stage II	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Renal and urinary disorders	1	(0.0)	1	0.08	0			
Renal cyst	1	(0.0)	1	0.08	0			
Gastrointestinal disorders	1	(0.0)	1	0.04	2	(0.1)	2	0.13
Large intestine polyp	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Gastric dysplasia	0				1	(0.0)	1	0.08
Surgical and medical procedures	0				1	(0.0)	1	0.04
Skin neoplasm excision	0				1	(0.0)	1	0.04

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.70 Neoplasms (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	17	(0.9)	20	1.36	22	(1.2)	26	1.67
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	(0.8)	18	1.21	19	(1.0)	23	1.48
Pancreatic neoplasm	2	(0.1)	2	0.15	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Colorectal cancer	2	(0.1)	2	0.14	0			
Metastases to liver	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Gastric cancer	1	(0.1)	1	0.09	0			
Lung cancer metastatic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Small cell lung cancer	1	(0.1)	1	0.09	0			
Basal cell carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Invasive ductal breast carcinoma	1	(0.1)	1	0.05	0			
Invasive lobular breast carcinoma	1	(0.1)	1	0.05	0			
Pancreatic carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Benign renal neoplasm	0				1	(0.1)	1	0.05
Bowen's disease	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Invasive breast carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma	0				1	(0.1)	1	0.05
Uterine leiomyoma	0				1	(0.1)	1	0.05
Small intestine neuroendocrine tumour	0				1	(0.1)	1	0.09
Uterine cancer	0				1	(0.1)	1	0.09
Colon cancer	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma in situ	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Colon cancer stage II	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Renal and urinary disorders	1	(0.1)	1	0.09	0			
Renal cyst	1	(0.1)	1	0.09	0			
Gastrointestinal disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Large intestine polyp	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Gastric dysplasia	0				1	(0.1)	1	0.09
Surgical and medical procedures	0				1	(0.1)	1	0.05
Skin neoplasm excision	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.71 Neoplasms (predefined MedDRA search) - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	62	(2.9)	74	4.44	66	(3.0)	86	5.18
Serious								
Yes	17	(0.8)	20	1.16	22	(1.0)	26	1.43
No	49	(2.3)	54	3.29	50	(2.3)	60	3.75
Missing	0				0			
Severity								
Severe	6	(0.3)	7	0.34	13	(0.6)	17	0.92
Moderate	15	(0.7)	17	1.03	11	(0.5)	12	0.64
Mild	45	(2.1)	50	3.07	48	(2.2)	57	3.62
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	62	(2.9)	74	4.44	66	(3.0)	86	5.18
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	62	(2.9)	74	4.44	66	(3.0)	86	5.18
NA	0				0			
Missing	0				0			
Outcome								
Fatal	3	(0.1)	4	0.18	2	(0.1)	2	0.12
Not recovered/not resolved	35	(1.6)	41	2.51	45	(2.1)	56	3.47
Recovered/resolved with sequelae	0				0			
Recovering/resolving	5	(0.2)	6	0.35	5	(0.2)	5	0.34
Recovered/resolved	23	(1.1)	23	1.40	21	(1.0)	23	1.25
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.72 Neoplasms (predefined MedDRA search) - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	54	(2.9)	66	4.27	57	(3.0)	75	4.80
Serious								
Yes	17	(0.9)	20	1.33	22	(1.2)	26	1.65
No	41	(2.2)	46	2.93	41	(2.2)	49	3.16
Missing	0				0			
Severity								
Severe	6	(0.3)	7	0.40	13	(0.7)	17	1.06
Moderate	15	(0.8)	17	1.19	11	(0.6)	12	0.74
Mild	37	(2.0)	42	2.68	39	(2.1)	46	3.00
Missing	0				0			
Related to basal insulin								
Probable	0				0			
Possible	0				0			
Unlikely	54	(2.9)	66	4.27	57	(3.0)	75	4.80
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	54	(2.9)	66	4.27	57	(3.0)	75	4.80
NA	0				0			
Missing	0				0			
Outcome								
Fatal	3	(0.2)	4	0.21	2	(0.1)	2	0.14
Not recovered/not resolved	30	(1.6)	36	2.36	38	(2.0)	47	3.05
Recovered/resolved with sequelae	0				0			
Recovering/resolving	4	(0.2)	5	0.29	4	(0.2)	4	0.28
Recovered/resolved	21	(1.1)	21	1.40	20	(1.1)	22	1.33
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.73 Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - in- trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	62	(2.9)	74	4.44	66	(3.0)	86	5.18
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	35	(1.6)	43	2.56	29	(1.3)	43	2.46
Colon adenoma	3	(0.1)	3	0.20	0			
Eye naevus	3	(0.1)	4	0.26	0			
Haemangioma of liver	2	(0.1)	2	0.14	0			
Pancreatic neoplasm	2	(0.1)	2	0.13	0			
Seborrhoeic keratosis	2	(0.1)	3	0.14	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Colorectal cancer	2	(0.1)	2	0.12	0			
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Benign neoplasm of thyroid gland	1	(0.0)	1	0.09	0			
Melanocytic naevus	1	(0.0)	1	0.09	0			
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Gastric cancer	1	(0.0)	1	0.08	0			
Bladder papilloma	1	(0.0)	1	0.08	0			
Lung cancer metastatic	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Skin papilloma	1	(0.0)	1	0.08	0			
Osteoma	1	(0.0)	1	0.08	0			
Small cell lung cancer	1	(0.0)	1	0.08	0			
Acrochordon	1	(0.0)	1	0.05	0			
Basal cell carcinoma	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Neoplasm skin	1	(0.0)	1	0.05	0			
Oral fibroma	1	(0.0)	1	0.05	0			
Prostate cancer	1	(0.0)	1	0.05	0			
Salivary gland neoplasm	1	(0.0)	1	0.05	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Invasive ductal breast carcinoma	1	(0.0)	1	0.04	0			
Invasive lobular breast carcinoma	1	(0.0)	1	0.04	0			
Lipoma	1	(0.0)	1	0.04	0			
Pancreatic carcinoma	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Renal neoplasm	1	(0.0)	1	0.04	0			
Squamous cell carcinoma of skin	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Uterine leiomyoma	0				5	(0.2)	5	0.35
Benign renal neoplasm	0				2	(0.1)	2	0.14
Adrenal adenoma	0				2	(0.1)	2	0.16
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Bowen's disease	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Gastrointestinal tract adenoma	0				1	(0.0)	1	0.04
Invasive breast carcinoma	0				1	(0.0)	1	0.04
Malignant melanoma	0				1	(0.0)	1	0.04
Malignant peritoneal neoplasm	0				1	(0.0)	1	0.04
Metastases to bone marrow	0				1	(0.0)	1	0.04
Metastases to lymph nodes	0				1	(0.0)	1	0.04
Myxoma	0				1	(0.0)	1	0.04
Prostatic adenoma	0				1	(0.0)	1	0.04
Renal hamartoma	0				1	(0.0)	1	0.04
Small intestine neuroendocrine tumour	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Uterine cancer	0				1	(0.0)	1	0.08
Colon cancer	0				1	(0.0)	1	0.05
Dysplastic naevus	0				1	(0.0)	1	0.05
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Malignant melanoma in situ	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Breast cancer	0				1	(0.0)	1	0.08
Colon cancer stage II	0				1	(0.0)	1	0.08
Lymphangioma	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Gastrointestinal disorders	8	(0.4)	8	0.42	13	(0.6)	15	0.87
Large intestine polyp	4	(0.2)	4	0.21	6	(0.3)	7	0.35
Gastric polyps	2	(0.1)	2	0.12	4	(0.2)	4	0.31
Rectal polyp	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Crohn's disease	0				1	(0.0)	1	0.05
Gastric dysplasia	0				1	(0.0)	1	0.08
Renal and urinary disorders	7	(0.3)	7	0.45	5	(0.2)	5	0.30
Renal cyst	7	(0.3)	7	0.45	5	(0.2)	5	0.30
Musculoskeletal and connective tissue disorders	4	(0.2)	4	0.23	2	(0.1)	2	0.12
Synovial cyst	3	(0.1)	3	0.19	1	(0.0)	1	0.04
Bone cyst	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Reproductive system and breast disorders	4	(0.2)	4	0.21	2	(0.1)	2	0.14
Uterine polyp	2	(0.1)	2	0.09	0			
Cervical polyp	1	(0.0)	1	0.08	0			
Ovarian cyst	1	(0.0)	1	0.05	0			
Testicular cyst	0				1	(0.0)	1	0.04
Fibrocystic breast disease	0				1	(0.0)	1	0.09
Hepatobiliary disorders	2	(0.1)	2	0.17	4	(0.2)	4	0.31
Gallbladder polyp	2	(0.1)	2	0.17	3	(0.1)	3	0.26
Hepatic cyst	0				1	(0.0)	1	0.05
Investigations	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Prostatic specific antigen increased	2	(0.1)	2	0.09	0			
Carbohydrate antigen 19-9 increased	0				1	(0.0)	1	0.04
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.09	6	(0.3)	6	0.39
Dermal cyst	1	(0.0)	1	0.09	4	(0.2)	4	0.26
Actinic keratosis	0				1	(0.0)	1	0.05
Leukoplakia	0				1	(0.0)	1	0.08
Surgical and medical procedures	1	(0.0)	1	0.09	2	(0.1)	2	0.09
Skin neoplasm excision	1	(0.0)	1	0.09	1	(0.0)	1	0.04
Large intestinal polypectomy	0				1	(0.0)	1	0.05
Infections and infestations	1	(0.0)	1	0.08	1	(0.0)	1	0.09
Infected dermal cyst	1	(0.0)	1	0.08	0			
Infected cyst	0				1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.05	3	(0.1)	3	0.24
Laryngeal cyst	1	(0.0)	1	0.05	0			
Paranasal cyst	0				2	(0.1)	2	0.16
Vocal cord polyp	0				1	(0.0)	1	0.08
General disorders and administration site conditions	0				2	(0.1)	2	0.12
Cyst	0				2	(0.1)	2	0.12

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.74 Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - in- trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	54	(2.9)	66	4.27	57	(3.0)	75	4.80
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	31	(1.6)	39	2.52	27	(1.4)	40	2.52
Colon adenoma	3	(0.2)	3	0.23	0			
Pancreatic neoplasm	2	(0.1)	2	0.14	0			
Seborrhoeic keratosis	2	(0.1)	3	0.16	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Colorectal cancer	2	(0.1)	2	0.14	0			
Eye naevus	2	(0.1)	3	0.19	0			
Metastases to liver	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Gastric cancer	1	(0.1)	1	0.09	0			
Bladder papilloma	1	(0.1)	1	0.09	0			
Lung cancer metastatic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Skin papilloma	1	(0.1)	1	0.09	0			
Osteoma	1	(0.1)	1	0.09	0			
Small cell lung cancer	1	(0.1)	1	0.09	0			
Acrochordon	1	(0.1)	1	0.05	0			
Basal cell carcinoma	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Haemangioma of liver	1	(0.1)	1	0.05	0			
Neoplasm skin	1	(0.1)	1	0.05	0			
Oral fibroma	1	(0.1)	1	0.05	0			
Prostate cancer	1	(0.1)	1	0.05	0			
Salivary gland neoplasm	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Invasive ductal breast carcinoma	1	(0.1)	1	0.05	0			
Invasive lobular breast carcinoma	1	(0.1)	1	0.05	0			
Lipoma	1	(0.1)	1	0.05	0			
Pancreatic carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Renal neoplasm	1	(0.1)	1	0.05	0			
Squamous cell carcinoma of skin	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Uterine leiomyoma	0				3	(0.2)	3	0.20
Adrenal adenoma	0				2	(0.1)	2	0.18
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Benign renal neoplasm	0				1	(0.1)	1	0.05
Bowen's disease	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Gastrointestinal tract adenoma	0				1	(0.1)	1	0.05
Invasive breast carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma	0				1	(0.1)	1	0.05
Malignant peritoneal neoplasm	0				1	(0.1)	1	0.05
Metastases to bone marrow	0				1	(0.1)	1	0.05
Metastases to lymph nodes	0				1	(0.1)	1	0.05
Myxoma	0				1	(0.1)	1	0.05
Prostatic adenoma	0				1	(0.1)	1	0.05
Renal hamartoma	0				1	(0.1)	1	0.05
Small intestine neuroendocrine tumour	0				1	(0.1)	1	0.09
Uterine cancer	0				1	(0.1)	1	0.09
Colon cancer	0				1	(0.1)	1	0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ11NAM != "" & (ANL01FL) == "Y"

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Dysplastic naevus	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma in situ	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Breast cancer	0				1	(0.1)	1	0.09
Colon cancer stage II	0				1	(0.1)	1	0.09
Lymphangioma	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Gastrointestinal disorders	8	(0.4)	8	0.49	11	(0.6)	13	0.79
Large intestine polyp	4	(0.2)	4	0.24	6	(0.3)	7	0.40
Gastric polyps	2	(0.1)	2	0.14	2	(0.1)	2	0.14
Rectal polyp	2	(0.1)	2	0.10	2	(0.1)	2	0.10
Crohn's disease	0				1	(0.1)	1	0.05
Gastric dysplasia	0				1	(0.1)	1	0.09
Renal and urinary disorders	7	(0.4)	7	0.52	4	(0.2)	4	0.24
Renal cyst	7	(0.4)	7	0.52	4	(0.2)	4	0.24
Reproductive system and breast disorders	4	(0.2)	4	0.25	1	(0.1)	1	0.05
Uterine polyp	2	(0.1)	2	0.10	0			
Cervical polyp	1	(0.1)	1	0.09	0			
Ovarian cyst	1	(0.1)	1	0.05	0			
Testicular cyst	0				1	(0.1)	1	0.05
Musculoskeletal and connective tissue disorders	3	(0.2)	3	0.16	2	(0.1)	2	0.14
Synovial cyst	2	(0.1)	2	0.11	1	(0.1)	1	0.05
Bone cyst	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Investigations	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Prostatic specific antigen increased	2	(0.1)	2	0.10	0			
Carbohydrate antigen 19-9 increased	0				1	(0.1)	1	0.05
Hepatobiliary disorders	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Gallbladder polyp	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Hepatic cyst	0				1	(0.1)	1	0.05
Infections and infestations	1	(0.1)	1	0.09	0			
Infected dermal cyst	1	(0.1)	1	0.09	0			
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.05	3	(0.2)	3	0.27
Laryngeal cyst	1	(0.1)	1	0.05	0			
Paranasal cyst	0				2	(0.1)	2	0.18
Vocal cord polyp	0				1	(0.1)	1	0.09
Skin and subcutaneous tissue disorders	0				5	(0.3)	5	0.34
Dermal cyst	0				3	(0.2)	3	0.20
Actinic keratosis	0				1	(0.1)	1	0.05
Leukoplakia	0				1	(0.1)	1	0.09
General disorders and administration site conditions	0				2	(0.1)	2	0.14
Cyst	0				2	(0.1)	2	0.14

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

Neoplasms (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - 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	0			2	(0.1)	2 0.10
Skin neoplasm excision	0			1	(0.1)	1 0.05
Large intestinal polypectomy	0			1	(0.1)	1 0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.75 Neoplasms (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	17	(0.8)	20	1.16	22	(1.0)	26	1.43
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	(0.7)	18	1.03	19	(0.9)	23	1.26
Pancreatic neoplasm	2	(0.1)	2	0.13	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.12	0			
Colorectal cancer	2	(0.1)	2	0.12	0			
Metastases to liver	2	(0.1)	2	0.09	1	(0.0)	1	0.04
Chronic myeloid leukaemia	1	(0.0)	1	0.08	0			
Gastric cancer	1	(0.0)	1	0.08	0			
Lung cancer metastatic	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Small cell lung cancer	1	(0.0)	1	0.08	0			
Basal cell carcinoma	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Glioblastoma multiforme	1	(0.0)	1	0.05	0			
Bladder cancer	1	(0.0)	1	0.04	0			
Invasive ductal breast carcinoma	1	(0.0)	1	0.04	0			
Invasive lobular breast carcinoma	1	(0.0)	1	0.04	0			
Pancreatic carcinoma	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Lung adenocarcinoma	0				2	(0.1)	2	0.16
Benign renal neoplasm	0				1	(0.0)	1	0.04
Bowen's disease	0				1	(0.0)	1	0.04
Breast cancer metastatic	0				1	(0.0)	1	0.04
Endometrial adenocarcinoma	0				1	(0.0)	1	0.04
Invasive breast carcinoma	0				1	(0.0)	1	0.04
Malignant melanoma	0				1	(0.0)	1	0.04
Uterine leiomyoma	0				1	(0.0)	1	0.04
Small intestine neuroendocrine tumour	0				1	(0.0)	1	0.08
Uterine cancer	0				1	(0.0)	1	0.08
Colon cancer	0				1	(0.0)	1	0.05
Hepatocellular carcinoma	0				1	(0.0)	1	0.05
Malignant melanoma in situ	0				1	(0.0)	1	0.05
Ovarian cancer metastatic	0				1	(0.0)	1	0.05
Renal cell carcinoma	0				1	(0.0)	1	0.05
Adenocarcinoma of colon	0				1	(0.0)	1	0.08
Colon cancer stage II	0				1	(0.0)	1	0.08
Pancreatic carcinoma metastatic	0				1	(0.0)	1	0.08
Renal and urinary disorders	1	(0.0)	1	0.08	0			
Renal cyst	1	(0.0)	1	0.08	0			
Gastrointestinal disorders	1	(0.0)	1	0.04	2	(0.1)	2	0.12
Large intestine polyp	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Gastric dysplasia	0				1	(0.0)	1	0.08
Surgical and medical procedures	0				1	(0.0)	1	0.04
Skin neoplasm excision	0				1	(0.0)	1	0.04

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.76 Neoplasms (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	17	(0.9)	20	1.33	22	(1.2)	26	1.65
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15	(0.8)	18	1.19	19	(1.0)	23	1.45
Pancreatic neoplasm	2	(0.1)	2	0.14	0			
Adenocarcinoma pancreas	2	(0.1)	2	0.14	0			
Colorectal cancer	2	(0.1)	2	0.14	0			
Metastases to liver	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Chronic myeloid leukaemia	1	(0.1)	1	0.09	0			
Gastric cancer	1	(0.1)	1	0.09	0			
Lung cancer metastatic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Small cell lung cancer	1	(0.1)	1	0.09	0			
Basal cell carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Glioblastoma multiforme	1	(0.1)	1	0.05	0			
Bladder cancer	1	(0.1)	1	0.05	0			
Invasive ductal breast carcinoma	1	(0.1)	1	0.05	0			
Invasive lobular breast carcinoma	1	(0.1)	1	0.05	0			
Pancreatic carcinoma	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Lung adenocarcinoma	0				2	(0.1)	2	0.18
Benign renal neoplasm	0				1	(0.1)	1	0.05
Bowen's disease	0				1	(0.1)	1	0.05
Breast cancer metastatic	0				1	(0.1)	1	0.05
Endometrial adenocarcinoma	0				1	(0.1)	1	0.05
Invasive breast carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma	0				1	(0.1)	1	0.05
Uterine leiomyoma	0				1	(0.1)	1	0.05
Small intestine neuroendocrine tumour	0				1	(0.1)	1	0.09
Uterine cancer	0				1	(0.1)	1	0.09
Colon cancer	0				1	(0.1)	1	0.05
Hepatocellular carcinoma	0				1	(0.1)	1	0.05
Malignant melanoma in situ	0				1	(0.1)	1	0.05
Ovarian cancer metastatic	0				1	(0.1)	1	0.05
Renal cell carcinoma	0				1	(0.1)	1	0.05
Adenocarcinoma of colon	0				1	(0.1)	1	0.09
Colon cancer stage II	0				1	(0.1)	1	0.09
Pancreatic carcinoma metastatic	0				1	(0.1)	1	0.09
Renal and urinary disorders	1	(0.1)	1	0.09	0			
Renal cyst	1	(0.1)	1	0.09	0			
Gastrointestinal disorders	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Large intestine polyp	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Gastric dysplasia	0				1	(0.1)	1	0.09
Surgical and medical procedures	0				1	(0.1)	1	0.05
Skin neoplasm excision	0				1	(0.1)	1	0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.77 Diabetic retinopathy or maculopathy (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	108	(5.0)	135	9.82	116	(5.3)	145	10.37
Serious								
Yes	2	(0.1)	2	0.16	3	(0.1)	4	0.29
No	106	(4.9)	133	9.66	114	(5.3)	141	10.08
Missing	0				0			
Severity								
Severe	1	(0.0)	1	0.04	2	(0.1)	2	0.12
Moderate	20	(0.9)	27	1.99	23	(1.1)	30	1.97
Mild	90	(4.1)	107	7.78	94	(4.3)	113	8.27
Missing	0				0			
Related to basal insulin								
Probable	4	(0.2)	4	0.30	1	(0.0)	1	0.08
Possible	14	(0.6)	15	1.24	11	(0.5)	20	1.49
Unlikely	92	(4.2)	116	8.28	104	(4.8)	124	8.80
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	107	(4.9)	134	9.74	115	(5.3)	144	10.29
NA	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	98	(4.5)	121	8.82	102	(4.7)	120	8.56
Recovered/resolved with sequelae	0				0			
Recovering/resolving	5	(0.2)	5	0.32	1	(0.0)	1	0.08
Recovered/resolved	7	(0.3)	9	0.67	14	(0.6)	23	1.69
Unknown	0				1	(0.0)	1	0.04
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.78 Diabetic retinopathy or maculopathy (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	86	(4.6)	109	8.51	95	(5.1)	120	9.29
Serious								
Yes	2	(0.1)	2	0.18	3	(0.2)	4	0.33
No	84	(4.5)	107	8.32	93	(5.0)	116	8.96
Missing	0				0			
Severity								
Severe	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Moderate	17	(0.9)	23	1.86	21	(1.1)	28	2.06
Mild	70	(3.7)	85	6.60	75	(4.0)	90	7.08
Missing	0				0			
Related to basal insulin								
Probable	3	(0.2)	3	0.23	1	(0.1)	1	0.09
Possible	9	(0.5)	10	0.88	9	(0.5)	18	1.51
Unlikely	76	(4.0)	96	7.39	85	(4.5)	101	7.69
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	85	(4.5)	108	8.42	94	(5.0)	119	9.20
NA	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	77	(4.1)	96	7.47	81	(4.3)	96	7.30
Recovered/resolved with sequelae	0				0			
Recovering/resolving	5	(0.3)	5	0.38	1	(0.1)	1	0.09
Recovered/resolved	6	(0.3)	8	0.66	13	(0.7)	22	1.84
Unknown	0				1	(0.1)	1	0.05
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.79 Diabetic retinopathy or maculopathy (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	108	(5.0)	135	9.82	116	(5.3)	145	10.37
Eye disorders	107	(4.9)	131	9.55	116	(5.3)	145	10.37
Diabetic retinopathy	64	(3.0)	70	5.14	72	(3.3)	76	5.44
Macular oedema	12	(0.6)	13	0.99	5	(0.2)	5	0.31
Retinopathy hypertensive	8	(0.4)	9	0.64	5	(0.2)	5	0.37
Diabetic retinal oedema	6	(0.3)	6	0.50	10	(0.5)	11	0.75
Retinal haemorrhage	4	(0.2)	4	0.28	0			
Non-proliferative retinopathy	3	(0.1)	4	0.35	4	(0.2)	4	0.34
Vitreous detachment	3	(0.1)	3	0.17	2	(0.1)	2	0.19
Epiretinal membrane	2	(0.1)	2	0.17	3	(0.1)	3	0.22
Vitreous haemorrhage	2	(0.1)	2	0.16	2	(0.1)	2	0.13
Arteriosclerotic retinopathy	2	(0.1)	2	0.14	0			
Age-related macular degeneration	2	(0.1)	2	0.12	0			
Retinal vascular disorder	1	(0.0)	1	0.09	1	(0.0)	1	0.08
Dry age-related macular degeneration	1	(0.0)	1	0.08	0			
Retinal exudates	1	(0.0)	1	0.08	2	(0.1)	2	0.16
Retinal vein occlusion	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Retinal deposits	1	(0.0)	1	0.08	0			
Retinal drusen	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Retinal scar	1	(0.0)	1	0.08	0			
Post thrombotic retinopathy	1	(0.0)	1	0.05	0			
Retinal aneurysm	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Retinal tear	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Amaurosis fugax	1	(0.0)	1	0.04	0			
Maculopathy	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Retinal degeneration	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Visual impairment	1	(0.0)	1	0.04	2	(0.1)	10	0.77
Macular degeneration	0				3	(0.1)	3	0.17
Vitreous floaters	0				3	(0.1)	3	0.27
Retinal artery occlusion	0				2	(0.1)	2	0.09
Retinal detachment	0				2	(0.1)	2	0.13
Retinopathy	0				2	(0.1)	2	0.17
Cystoid macular oedema	0				1	(0.0)	1	0.04
Scintillating scotoma	0				1	(0.0)	1	0.05
Chorioretinal atrophy	0				1	(0.0)	1	0.08
Macular hole	0				1	(0.0)	1	0.08
Visual acuity reduced	0				1	(0.0)	1	0.08
Photopsia	0				1	(0.0)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	(0.1)	4	0.26	0			
Eye naevus	3	(0.1)	4	0.26	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.80 Diabetic retinopathy or maculopathy (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	86	(4.6)	109	8.51	95	(5.1)	120	9.29
Eye disorders	86	(4.6)	106	8.31	95	(5.1)	120	9.29
Diabetic retinopathy	52	(2.8)	58	4.63	58	(3.1)	62	4.78
Macular oedema	9	(0.5)	9	0.71	4	(0.2)	4	0.25
Retinopathy hypertensive	6	(0.3)	7	0.52	5	(0.3)	5	0.42
Diabetic retinal oedema	4	(0.2)	4	0.37	9	(0.5)	10	0.76
Retinal haemorrhage	4	(0.2)	4	0.33	0			
Vitreous detachment	3	(0.2)	3	0.20	0			
Vitreous haemorrhage	2	(0.1)	2	0.18	2	(0.1)	2	0.15
Age-related macular degeneration	2	(0.1)	2	0.14	0			
Dry age-related macular degeneration	1	(0.1)	1	0.09	0			
Epiretinal membrane	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Retinal exudates	1	(0.1)	1	0.09	2	(0.1)	2	0.19
Retinal vein occlusion	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Non-proliferative retinopathy	1	(0.1)	2	0.18	2	(0.1)	2	0.18
Retinal deposits	1	(0.1)	1	0.09	0			
Retinal drusen	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Retinal scar	1	(0.1)	1	0.09	0			
Post thrombotic retinopathy	1	(0.1)	1	0.05	0			
Retinal aneurysm	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Retinal tear	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Amaurosis fugax	1	(0.1)	1	0.05	0			
Arteriosclerotic retinopathy	1	(0.1)	1	0.05	0			
Maculopathy	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Retinal degeneration	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Visual impairment	1	(0.1)	1	0.05	2	(0.1)	10	0.89
Macular degeneration	0				3	(0.2)	3	0.20
Retinal artery occlusion	0				2	(0.1)	2	0.11
Retinal detachment	0				2	(0.1)	2	0.15
Cystoid macular oedema	0				1	(0.1)	1	0.05
Retinal vascular disorder	0				1	(0.1)	1	0.09
Scintillating scotoma	0				1	(0.1)	1	0.05
Chorioretinal atrophy	0				1	(0.1)	1	0.09
Macular hole	0				1	(0.1)	1	0.09
Retinopathy	0				1	(0.1)	1	0.09
Vitreous floaters	0				1	(0.1)	1	0.09
Visual acuity reduced	0				1	(0.1)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	(0.1)	3	0.20	0			
Eye naevus	2	(0.1)	3	0.20	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.81 Diabetic retinopathy or maculopathy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	2	(0.1)	2	0.16	3	(0.1)	4	0.29
Eye disorders	2	(0.1)	2	0.16	3	(0.1)	4	0.29
Retinal vein occlusion	1	(0.0)	1	0.08	0			
Retinopathy hypertensive	1	(0.0)	1	0.08	0			
Diabetic retinal oedema	0				3	(0.1)	4	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ08NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:36 - taesocpt/taessocptdiaretsumontp3asas.txt

7.3.82 Diabetic retinopathy or maculopathy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	2	(0.1)	2	0.18	3	(0.2)	4	0.33
Eye disorders	2	(0.1)	2	0.18	3	(0.2)	4	0.33
Retinal vein occlusion	1	(0.1)	1	0.09	0			
Retinopathy hypertensive	1	(0.1)	1	0.09	0			
Diabetic retinal oedema	0				3	(0.2)	4	0.33

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ08NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:38 - taesocpt/taessocptdiaretsumontt2dsas.txt

7.3.83 Diabetic retinopathy or maculopathy (predefined MedDRA search) - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	111	(5.1)	138	9.85	116	(5.3)	145	10.22
Serious								
Yes	2	(0.1)	2	0.16	3	(0.1)	4	0.28
No	109	(5.0)	136	9.70	114	(5.3)	141	9.94
Missing	0				0			
Severity								
Severe	1	(0.0)	1	0.04	2	(0.1)	2	0.12
Moderate	22	(1.0)	29	2.05	23	(1.1)	30	1.94
Mild	91	(4.2)	108	7.76	94	(4.3)	113	8.16
Missing	0				0			
Related to basal insulin								
Probable	4	(0.2)	4	0.29	1	(0.0)	1	0.08
Possible	14	(0.6)	15	1.22	11	(0.5)	20	1.47
Unlikely	95	(4.4)	119	8.34	104	(4.8)	124	8.67
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	110	(5.1)	137	9.77	115	(5.3)	144	10.14
NA	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	101	(4.7)	124	8.87	102	(4.7)	120	8.44
Recovered/resolved with sequelae	0				0			
Recovering/resolving	5	(0.2)	5	0.32	1	(0.0)	1	0.08
Recovered/resolved	7	(0.3)	9	0.66	14	(0.6)	23	1.66
Unknown	0				1	(0.0)	1	0.04
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.84 Diabetic retinopathy or maculopathy (predefined MedDRA search) - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	89	(4.7)	112	8.57	95	(5.1)	120	9.13
Serious								
Yes	2	(0.1)	2	0.18	3	(0.2)	4	0.33
No	87	(4.6)	110	8.39	93	(5.0)	116	8.80
Missing	0				0			
Severity								
Severe	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Moderate	19	(1.0)	25	1.94	21	(1.1)	28	2.03
Mild	71	(3.8)	86	6.58	75	(4.0)	90	6.96
Missing	0				0			
Related to basal insulin								
Probable	3	(0.2)	3	0.23	1	(0.1)	1	0.09
Possible	9	(0.5)	10	0.87	9	(0.5)	18	1.48
Unlikely	79	(4.2)	99	7.46	85	(4.5)	101	7.55
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	88	(4.7)	111	8.48	94	(5.0)	119	9.04
NA	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	80	(4.3)	99	7.54	81	(4.3)	96	7.18
Recovered/resolved with sequelae	0				0			
Recovering/resolving	5	(0.3)	5	0.37	1	(0.1)	1	0.09
Recovered/resolved	6	(0.3)	8	0.65	13	(0.7)	22	1.81
Unknown	0				1	(0.1)	1	0.05
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.85 Diabetic retinopathy or maculopathy (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	111	(5.1)	138	9.85	116	(5.3)	145	10.22
Eye disorders	110	(5.1)	134	9.59	116	(5.3)	145	10.22
Diabetic retinopathy	65	(3.0)	71	5.15	72	(3.3)	76	5.36
Macular oedema	13	(0.6)	14	1.02	5	(0.2)	5	0.30
Retinopathy hypertensive	8	(0.4)	9	0.63	5	(0.2)	5	0.36
Diabetic retinal oedema	6	(0.3)	6	0.50	10	(0.5)	11	0.74
Retinal haemorrhage	4	(0.2)	4	0.28	0			
Non-proliferative retinopathy	3	(0.1)	4	0.34	4	(0.2)	4	0.34
Vitreous detachment	3	(0.1)	3	0.17	2	(0.1)	2	0.19
Epiretinal membrane	2	(0.1)	2	0.17	3	(0.1)	3	0.21
Vitreous haemorrhage	2	(0.1)	2	0.16	2	(0.1)	2	0.13
Arteriosclerotic retinopathy	2	(0.1)	2	0.14	0			
Age-related macular degeneration	2	(0.1)	2	0.12	0			
Visual impairment	2	(0.1)	2	0.09	2	(0.1)	10	0.76
Retinal vascular disorder	1	(0.0)	1	0.09	1	(0.0)	1	0.08
Dry age-related macular degeneration	1	(0.0)	1	0.08	0			
Retinal exudates	1	(0.0)	1	0.08	2	(0.1)	2	0.16
Retinal vein occlusion	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Retinal deposits	1	(0.0)	1	0.08	0			
Retinal drusen	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Retinal scar	1	(0.0)	1	0.08	0			
Post thrombotic retinopathy	1	(0.0)	1	0.05	0			
Retinal aneurysm	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Retinal tear	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Amaurosis fugax	1	(0.0)	1	0.04	0			
Maculopathy	1	(0.0)	1	0.04	1	(0.0)	1	0.04
Retinal degeneration	1	(0.0)	1	0.04	1	(0.0)	1	0.08
Macular degeneration	0				3	(0.1)	3	0.17
Vitreous floaters	0				3	(0.1)	3	0.26
Retinal artery occlusion	0				2	(0.1)	2	0.09
Retinal detachment	0				2	(0.1)	2	0.13
Retinopathy	0				2	(0.1)	2	0.17
Cystoid macular oedema	0				1	(0.0)	1	0.04
Scintillating scotoma	0				1	(0.0)	1	0.05
Chorioretinal atrophy	0				1	(0.0)	1	0.08
Macular hole	0				1	(0.0)	1	0.08
Visual acuity reduced	0				1	(0.0)	1	0.08
Photopsia	0				1	(0.0)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3	(0.1)	4	0.26	0			
Eye naevus	3	(0.1)	4	0.26	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.86 Diabetic retinopathy or maculopathy (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	89	(4.7)	112	8.57	95	(5.1)	120	9.13
Eye disorders	89	(4.7)	109	8.37	95	(5.1)	120	9.13
Diabetic retinopathy	53	(2.8)	59	4.65	58	(3.1)	62	4.69
Macular oedema	10	(0.5)	10	0.75	4	(0.2)	4	0.24
Retinopathy hypertensive	6	(0.3)	7	0.51	5	(0.3)	5	0.41
Diabetic retinal oedema	4	(0.2)	4	0.36	9	(0.5)	10	0.75
Retinal haemorrhage	4	(0.2)	4	0.32	0			
Vitreous detachment	3	(0.2)	3	0.19	0			
Vitreous haemorrhage	2	(0.1)	2	0.18	2	(0.1)	2	0.14
Age-related macular degeneration	2	(0.1)	2	0.14	0			
Visual impairment	2	(0.1)	2	0.10	2	(0.1)	10	0.87
Dry age-related macular degeneration	1	(0.1)	1	0.09	0			
Epiretinal membrane	1	(0.1)	1	0.09	2	(0.1)	2	0.14
Retinal exudates	1	(0.1)	1	0.09	2	(0.1)	2	0.18
Retinal vein occlusion	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Non-proliferative retinopathy	1	(0.1)	2	0.18	2	(0.1)	2	0.18
Retinal deposits	1	(0.1)	1	0.09	0			
Retinal drusen	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Retinal scar	1	(0.1)	1	0.09	0			
Post thrombotic retinopathy	1	(0.1)	1	0.05	0			
Retinal aneurysm	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Retinal tear	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Amaurosis fugax	1	(0.1)	1	0.05	0			
Arteriosclerotic retinopathy	1	(0.1)	1	0.05	0			
Maculopathy	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Retinal degeneration	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Macular degeneration	0				3	(0.2)	3	0.19
Retinal artery occlusion	0				2	(0.1)	2	0.10
Retinal detachment	0				2	(0.1)	2	0.14
Cystoid macular oedema	0				1	(0.1)	1	0.05
Retinal vascular disorder	0				1	(0.1)	1	0.09
Scintillating scotoma	0				1	(0.1)	1	0.05
Chorioretinal atrophy	0				1	(0.1)	1	0.09
Macular hole	0				1	(0.1)	1	0.09
Retinopathy	0				1	(0.1)	1	0.09
Vitreous floaters	0				1	(0.1)	1	0.09
Visual acuity reduced	0				1	(0.1)	1	0.09
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	(0.1)	3	0.19	0			
Eye naevus	2	(0.1)	3	0.19	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.87 Diabetic retinopathy or maculopathy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	2	(0.1)	2	0.16	3	(0.1)	4	0.28
Eye disorders	2	(0.1)	2	0.16	3	(0.1)	4	0.28
Retinal vein occlusion	1	(0.0)	1	0.08	0			
Retinopathy hypertensive	1	(0.0)	1	0.08	0			
Diabetic retinal oedema	0				3	(0.1)	4	0.28

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ08NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:45 - taesocpt/taessocptdiaretsumintp3asas.txt

7.3.88 Diabetic retinopathy or maculopathy (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	2	(0.1)	2	0.18	3	(0.2)	4	0.33
Eye disorders	2	(0.1)	2	0.18	3	(0.2)	4	0.33
Retinal vein occlusion	1	(0.1)	1	0.09	0			
Retinopathy hypertensive	1	(0.1)	1	0.09	0			
Diabetic retinal oedema	0				3	(0.2)	4	0.33

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): INTRDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ08NAM != "" & AESER == "Y" & (ANL01FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:48 - taesocpt/taessocptdiaretsumintt2dsas.txt

7.3.89 Injection site reactions (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	42	(1.9)	81	6.04	37	(1.7)	67	3.97
Serious								
Yes	0				0			
No	42	(1.9)	81	6.04	37	(1.7)	67	3.97
Missing	0				0			
Severity								
Severe	0				0			
Moderate	4	(0.2)	4	0.25	3	(0.1)	3	0.14
Mild	40	(1.8)	77	5.78	34	(1.6)	64	3.83
Missing	0				0			
Related to basal insulin								
Probable	18	(0.8)	32	2.38	24	(1.1)	52	3.01
Possible	8	(0.4)	15	1.15	9	(0.4)	9	0.58
Unlikely	21	(1.0)	34	2.50	6	(0.3)	6	0.37
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.0)	1	0.08	0			
No	41	(1.9)	80	5.96	37	(1.7)	67	3.97
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	1	(0.0)	2	0.09	2	(0.1)	2	0.09
Recovered/resolved with sequelae	0				0			
Recovering/resolving	3	(0.1)	4	0.32	2	(0.1)	2	0.13
Recovered/resolved	40	(1.8)	75	5.63	34	(1.6)	63	3.75
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.90 Injection site reactions (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	41	(2.2)	79	6.75	35	(1.9)	65	4.37
Serious								
Yes	0				0			
No	41	(2.2)	79	6.75	35	(1.9)	65	4.37
Missing	0				0			
Severity								
Severe	0				0			
Moderate	4	(0.2)	4	0.29	3	(0.2)	3	0.16
Mild	39	(2.1)	75	6.46	32	(1.7)	62	4.21
Missing	0				0			
Related to basal insulin								
Probable	17	(0.9)	31	2.64	22	(1.2)	50	3.26
Possible	8	(0.4)	15	1.33	9	(0.5)	9	0.68
Unlikely	20	(1.1)	33	2.78	6	(0.3)	6	0.43
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.1)	1	0.09	0			
No	40	(2.1)	78	6.66	35	(1.9)	65	4.37
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	1	(0.1)	2	0.10	2	(0.1)	2	0.11
Recovered/resolved with sequelae	0				0			
Recovering/resolving	3	(0.2)	4	0.37	2	(0.1)	2	0.15
Recovered/resolved	39	(2.1)	73	6.28	32	(1.7)	61	4.12
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.91 Injection site reactions (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	42	(1.9)	81	6.04	37	(1.7)	67	3.97
General disorders and administration site conditions	41	(1.9)	80	5.96	37	(1.7)	67	3.97
Injection site reaction	15	(0.7)	29	2.23	6	(0.3)	8	0.46
Injection site pruritus	4	(0.2)	19	1.43	1	(0.0)	1	0.08
Injection site pain	3	(0.1)	3	0.24	13	(0.6)	31	1.67
Injection site erythema	3	(0.1)	5	0.36	4	(0.2)	4	0.19
Injection site bruising	3	(0.1)	3	0.20	5	(0.2)	5	0.26
Injection site swelling	2	(0.1)	2	0.16	1	(0.0)	1	0.08
Injection site haematoma	2	(0.1)	6	0.47	3	(0.1)	8	0.63
Injection site haemorrhage	2	(0.1)	2	0.16	2	(0.1)	2	0.13
Injection site hypersensitivity	2	(0.1)	2	0.09	0			
Injection site mass	2	(0.1)	2	0.09	1	(0.0)	1	0.09
Injection site urticaria	1	(0.0)	2	0.19	1	(0.0)	1	0.05
Application site bruise	1	(0.0)	1	0.08	0			
Application site pruritus	1	(0.0)	1	0.08	0			
Injection site rash	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Injection site dermatitis	1	(0.0)	1	0.05	0			
Vessel puncture site bruise	1	(0.0)	1	0.04	0			
Injection site induration	0				2	(0.1)	2	0.12
Injection site hypertrophy	0				1	(0.0)	1	0.05
Injection site oedema	0				1	(0.0)	1	0.08
Infections and infestations	1	(0.0)	1	0.08	0			
Injection site abscess	1	(0.0)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.92 Injection site reactions (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	41	(2.2)	79	6.75	35	(1.9)	65	4.37
General disorders and administration site conditions	40	(2.1)	78	6.66	35	(1.9)	65	4.37
Injection site reaction	15	(0.8)	29	2.57	6	(0.3)	8	0.53
Injection site pruritus	4	(0.2)	19	1.66	1	(0.1)	1	0.09
Injection site pain	3	(0.2)	3	0.27	12	(0.6)	30	1.82
Injection site erythema	3	(0.2)	5	0.42	4	(0.2)	4	0.22
Injection site bruising	3	(0.2)	3	0.23	5	(0.3)	5	0.30
Injection site swelling	2	(0.1)	2	0.18	1	(0.1)	1	0.09
Injection site haematoma	2	(0.1)	6	0.55	3	(0.2)	8	0.73
Injection site haemorrhage	2	(0.1)	2	0.18	2	(0.1)	2	0.15
Injection site hypersensitivity	2	(0.1)	2	0.11	0			
Injection site mass	2	(0.1)	2	0.11	0			
Application site bruise	1	(0.1)	1	0.09	0			
Application site pruritus	1	(0.1)	1	0.09	0			
Injection site rash	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Injection site dermatitis	1	(0.1)	1	0.05	0			
Vessel puncture site bruise	1	(0.1)	1	0.05	0			
Injection site induration	0				2	(0.1)	2	0.14
Injection site hypertrophy	0				1	(0.1)	1	0.05
Injection site urticaria	0				1	(0.1)	1	0.05
Injection site oedema	0				1	(0.1)	1	0.09
Infections and infestations	1	(0.1)	1	0.09	0			
Injection site abscess	1	(0.1)	1	0.09	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ02NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:52 - taesocpt/taesocptinjreacsumontt2dsas.txt

7.3.93 Injection site reactions (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ02NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:54 - taesocpt/taessocptinjreacsumontp3asas.txt

7.3.94 Injection site reactions (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ02NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:01:56 - taesocpt/taessocptinjreacsumontt2dsas.txt

7.3.95 Systemic hypersensitivity reactions (reported by investigator) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	12	(0.6)	15	0.89	8	(0.4)	9	0.52
Serious								
Yes	2	(0.1)	2	0.12	1	(0.0)	1	0.08
No	11	(0.5)	13	0.77	7	(0.3)	8	0.45
Missing	0				0			
Severity								
Severe	3	(0.1)	3	0.22	2	(0.1)	2	0.12
Moderate	5	(0.2)	5	0.33	3	(0.1)	3	0.14
Mild	6	(0.3)	7	0.35	4	(0.2)	4	0.26
Missing	0				0			
Related to basal insulin								
Probable	3	(0.1)	5	0.26	1	(0.0)	1	0.08
Possible	3	(0.1)	4	0.22	3	(0.1)	4	0.21
Unlikely	5	(0.2)	5	0.34	4	(0.2)	4	0.23
Missing	1	(0.0)	1	0.08	0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	11	(0.5)	14	0.81	8	(0.4)	9	0.52
NA	0				0			
Missing	1	(0.0)	1	0.08	0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	1	(0.0)	1	0.08	1	(0.0)	1	0.09
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Recovered/resolved	10	(0.5)	13	0.74	7	(0.3)	7	0.39
Unknown	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eCRF: Electronic case report form, 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. Events reported in eCRF.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" &
(ANELFL) == "Y" & ACAT1 == "HYPERSENSITIVITY" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:07:53 - taesum/taehypersensinvsumontp3asas.txt

7.3.96 Systemic hypersensitivity reactions (reported by investigator) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	11	(0.6)	14	0.92	7	(0.4)	8	0.50
Serious								
Yes	2	(0.1)	2	0.14	1	(0.1)	1	0.09
No	10	(0.5)	12	0.78	6	(0.3)	7	0.41
Missing	0				0			
Severity								
Severe	2	(0.1)	2	0.14	2	(0.1)	2	0.14
Moderate	5	(0.3)	5	0.38	3	(0.2)	3	0.16
Mild	6	(0.3)	7	0.40	3	(0.2)	3	0.20
Missing	0				0			
Related to basal insulin								
Probable	3	(0.2)	5	0.30	1	(0.1)	1	0.09
Possible	3	(0.2)	4	0.25	3	(0.2)	4	0.25
Unlikely	4	(0.2)	4	0.29	3	(0.2)	3	0.16
Missing	1	(0.1)	1	0.09	0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	10	(0.5)	13	0.83	7	(0.4)	8	0.50
NA	0				0			
Missing	1	(0.1)	1	0.09	0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	1	(0.1)	1	0.09	0			
Recovered/resolved with sequelae	0				0			
Recovering/resolving	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Recovered/resolved	9	(0.5)	12	0.74	7	(0.4)	7	0.45
Unknown	0				0			
Missing	0				0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eCRF: Electronic case report form, 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. Events reported in eCRF.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & ACAT1 == "HYPERSENSITIVITY" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:07:55 - taesum/taehypersensinvsumontt2dsas.txt

7.3.97 Systemic hypersensitivity reactions (reported by investigator) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	12	(0.6)	15	0.89	8	(0.4)	9	0.52
Skin and subcutaneous tissue disorders	6	(0.3)	6	0.37	6	(0.3)	7	0.35
Urticaria	4	(0.2)	4	0.28	4	(0.2)	4	0.22
Angioedema	1	(0.0)	1	0.05	2	(0.1)	2	0.09
Pruritus	1	(0.0)	1	0.05	1	(0.0)	1	0.04
General disorders and administration site conditions	3	(0.1)	3	0.17	0			
Medical device site dermatitis	1	(0.0)	1	0.08	0			
Drug intolerance	1	(0.0)	1	0.05	0			
Swelling face	1	(0.0)	1	0.04	0			
Immune system disorders	2	(0.1)	2	0.17	1	(0.0)	1	0.08
Hypersensitivity	1	(0.0)	1	0.09	0			
Anaphylactic reaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Gastrointestinal disorders	2	(0.1)	2	0.09	0			
Diarrhoea	1	(0.0)	1	0.04	0			
Lip swelling	1	(0.0)	1	0.04	0			
Nervous system disorders	1	(0.0)	2	0.09	0			
Paraesthesia	1	(0.0)	2	0.09	0			
Respiratory, thoracic and mediastinal disorders	0				1	(0.0)	1	0.09
Rhinitis allergic	0				1	(0.0)	1	0.09

%: Percentage of subjects with one or more events, E: Number of adverse events, eCRF: Electronic case report form, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of 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. MedDRA version 24.1. Events reported in eCRF.

7.3.98 Systemic hypersensitivity reactions (reported by investigator) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	11	(0.6)	14	0.92	7	(0.4)	8	0.50
Skin and subcutaneous tissue disorders	6	(0.3)	6	0.43	6	(0.3)	7	0.41
Urticaria	4	(0.2)	4	0.32	4	(0.2)	4	0.25
Angioedema	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Pruritus	1	(0.1)	1	0.05	1	(0.1)	1	0.05
General disorders and administration site conditions	3	(0.2)	3	0.20	0			
Medical device site dermatitis	1	(0.1)	1	0.09	0			
Drug intolerance	1	(0.1)	1	0.05	0			
Swelling face	1	(0.1)	1	0.05	0			
Gastrointestinal disorders	2	(0.1)	2	0.10	0			
Diarrhoea	1	(0.1)	1	0.05	0			
Lip swelling	1	(0.1)	1	0.05	0			
Immune system disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Anaphylactic reaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Nervous system disorders	1	(0.1)	2	0.10	0			
Paraesthesia	1	(0.1)	2	0.10	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eCRF: Electronic case report form, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of 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. MedDRA version 24.1. Events reported in eCRF.

7.3.99 Systemic hypersensitivity reactions (reported by investigator) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Immune system disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Anaphylactic reaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.04	0			
Urticaria	1	(0.0)	1	0.04	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eCRF: Electronic case report form, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of 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. MedDRA version 24.1. Events reported in eCRF.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & ACAT1 == "HYPERSENSITIVITY" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:03 - taesocpt/taessocpthypersensinvsumontp3asas.txt

7.3.100 Systemic hypersensitivity reactions (reported by investigator) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Immune system disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Anaphylactic reaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	0			
Urticaria	1	(0.1)	1	0.05	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, eCRF: Electronic case report form, N: Number of subjects with one or more events, PYE: Patient years of exposure (1 PYE = 365.25 days), R: Rate (number of 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. MedDRA version 24.1. Events reported in eCRF.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & ACAT1 == "HYPERSENSITIVITY" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:06 - taesocpt/taessocpthypersensinvsumontt2dsas.txt

7.3.101 Hypersensitivity reactions (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	83	(3.8)	93	6.20	96	(4.4)	115	7.47
Serious								
Yes	2	(0.1)	2	0.12	1	(0.0)	1	0.08
No	82	(3.8)	91	6.08	95	(4.4)	114	7.39
Missing	0				0			
Severity								
Severe	3	(0.1)	3	0.22	1	(0.0)	1	0.08
Moderate	9	(0.4)	10	0.67	13	(0.6)	13	0.74
Mild	72	(3.3)	80	5.31	85	(3.9)	101	6.65
Missing	0				0			
Related to basal insulin								
Probable	4	(0.2)	6	0.35	1	(0.0)	1	0.08
Possible	5	(0.2)	5	0.40	3	(0.1)	4	0.25
Unlikely	75	(3.5)	81	5.38	92	(4.2)	110	7.14
Missing	1	(0.0)	1	0.08	0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	82	(3.8)	92	6.12	96	(4.4)	115	7.47
NA	0				0			
Missing	1	(0.0)	1	0.08	0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	22	(1.0)	22	1.69	30	(1.4)	31	2.27
Recovered/resolved with sequelae	0				0			
Recovering/resolving	2	(0.1)	2	0.16	6	(0.3)	6	0.34
Recovered/resolved	62	(2.9)	69	4.36	64	(2.9)	78	4.86
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.102 Hypersensitivity reactions (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	59	(3.1)	68	4.44	71	(3.8)	88	5.73
Serious								
Yes	2	(0.1)	2	0.14	1	(0.1)	1	0.09
No	58	(3.1)	66	4.30	70	(3.7)	87	5.63
Missing	0				0			
Severity								
Severe	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Moderate	8	(0.4)	9	0.67	10	(0.5)	10	0.53
Mild	50	(2.7)	57	3.63	62	(3.3)	77	5.10
Missing	0				0			
Related to basal insulin								
Probable	3	(0.2)	5	0.30	1	(0.1)	1	0.09
Possible	3	(0.2)	3	0.24	3	(0.2)	4	0.29
Unlikely	53	(2.8)	59	3.81	67	(3.6)	83	5.35
Missing	1	(0.1)	1	0.09	0			
Related to technical complaint for basal insulin								
Yes	0				0			
No	58	(3.1)	67	4.35	71	(3.8)	88	5.73
NA	0				0			
Missing	1	(0.1)	1	0.09	0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	12	(0.6)	12	0.86	15	(0.8)	16	1.01
Recovered/resolved with sequelae	0				0			
Recovering/resolving	2	(0.1)	2	0.18	6	(0.3)	6	0.39
Recovered/resolved	48	(2.6)	54	3.40	53	(2.8)	66	4.33
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.103 Hypersensitivity reactions (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	83	(3.8)	93	6.20	96	(4.4)	115	7.47
Skin and subcutaneous tissue disorders	51	(2.4)	52	3.33	58	(2.7)	63	4.09
Rash	14	(0.6)	14	0.95	11	(0.5)	12	0.62
Eczema	10	(0.5)	10	0.56	7	(0.3)	7	0.50
Dermatitis	7	(0.3)	7	0.55	7	(0.3)	8	0.51
Dermatitis contact	7	(0.3)	8	0.47	14	(0.6)	14	1.00
Urticaria	7	(0.3)	7	0.45	12	(0.6)	12	0.72
Rash erythematous	2	(0.1)	2	0.17	0			
Dermatitis allergic	2	(0.1)	2	0.09	1	(0.0)	1	0.08
Angioedema	1	(0.0)	1	0.05	3	(0.1)	3	0.18
Urticaria contact	1	(0.0)	1	0.05	0			
Dermatitis atopic	0				2	(0.1)	2	0.19
Skin reaction	0				1	(0.0)	1	0.08
Drug eruption	0				1	(0.0)	1	0.05
Pruritus allergic	0				1	(0.0)	1	0.08
Rash maculo-papular	0				1	(0.0)	1	0.08
General disorders and administration site conditions	22	(1.0)	26	1.88	25	(1.2)	32	2.10
Medical device site dermatitis	7	(0.3)	10	0.67	11	(0.5)	18	1.03
Medical device site rash	6	(0.3)	6	0.57	8	(0.4)	8	0.73
Injection site hypersensitivity	2	(0.1)	2	0.09	0			
Swelling face	2	(0.1)	2	0.14	2	(0.1)	2	0.12
Injection site urticaria	1	(0.0)	2	0.19	1	(0.0)	1	0.05
Injection site rash	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Injection site dermatitis	1	(0.0)	1	0.05	0			
Medical device site eczema	1	(0.0)	1	0.05	2	(0.1)	2	0.09
Medical device site hypersensitivity	1	(0.0)	1	0.05	0			
Immune system disorders	5	(0.2)	5	0.43	2	(0.1)	2	0.16
Hypersensitivity	3	(0.1)	3	0.27	1	(0.0)	1	0.08
Anaphylactic reaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Drug hypersensitivity	1	(0.0)	1	0.08	0			
Respiratory, thoracic and mediastinal disorders	3	(0.1)	3	0.22	10	(0.5)	14	0.94
Rhinitis allergic	2	(0.1)	2	0.14	6	(0.3)	10	0.64
Bronchospasm	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Allergic cough	0				2	(0.1)	2	0.17
Allergic bronchitis	0				1	(0.0)	1	0.05
Investigations	3	(0.1)	3	0.13	3	(0.1)	3	0.13
Blood immunoglobulin E increased	3	(0.1)	3	0.13	3	(0.1)	3	0.13
Eye disorders	2	(0.1)	3	0.17	1	(0.0)	1	0.04
Conjunctivitis allergic	2	(0.1)	3	0.17	0			
Eyelid oedema	0				1	(0.0)	1	0.04

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

Hypersensitivity reactions (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Gastrointestinal disorders	1	(0.0)	1	0.04	0			
Lip swelling	1	(0.0)	1	0.04	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.104 Hypersensitivity reactions (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	59	(3.1)	68	4.44	71	(3.8)	88	5.73
Skin and subcutaneous tissue disorders	41	(2.2)	42	2.75	44	(2.3)	49	3.22
Rash	11	(0.6)	11	0.77	11	(0.6)	12	0.71
Eczema	10	(0.5)	10	0.65	6	(0.3)	6	0.47
Urticaria	7	(0.4)	7	0.52	9	(0.5)	9	0.51
Dermatitis contact	5	(0.3)	6	0.32	8	(0.4)	8	0.51
Dermatitis	3	(0.2)	3	0.20	6	(0.3)	7	0.49
Dermatitis allergic	2	(0.1)	2	0.11	1	(0.1)	1	0.09
Rash erythematous	1	(0.1)	1	0.09	0			
Angioedema	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Urticaria contact	1	(0.1)	1	0.05	0			
Skin reaction	0				1	(0.1)	1	0.09
Drug eruption	0				1	(0.1)	1	0.05
Pruritus allergic	0				1	(0.1)	1	0.09
Rash maculo-papular	0				1	(0.1)	1	0.09
General disorders and administration site conditions	11	(0.6)	14	0.86	15	(0.8)	21	1.24
Medical device site dermatitis	4	(0.2)	7	0.45	8	(0.4)	14	0.76
Injection site hypersensitivity	2	(0.1)	2	0.11	0			
Injection site rash	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Injection site dermatitis	1	(0.1)	1	0.05	0			
Medical device site eczema	1	(0.1)	1	0.05	2	(0.1)	2	0.11
Medical device site hypersensitivity	1	(0.1)	1	0.05	0			
Swelling face	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Injection site urticaria	0				1	(0.1)	1	0.05
Medical device site rash	0				1	(0.1)	1	0.09
Immune system disorders	3	(0.2)	3	0.28	2	(0.1)	2	0.18
Anaphylactic reaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Drug hypersensitivity	1	(0.1)	1	0.09	0			
Hypersensitivity	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Investigations	3	(0.2)	3	0.15	3	(0.2)	3	0.15
Blood immunoglobulin E increased	3	(0.2)	3	0.15	3	(0.2)	3	0.15
Eye disorders	2	(0.1)	3	0.20	1	(0.1)	1	0.05
Conjunctivitis allergic	2	(0.1)	3	0.20	0			
Eyelid oedema	0				1	(0.1)	1	0.05
Respiratory, thoracic and mediastinal disorders	2	(0.1)	2	0.14	8	(0.4)	12	0.87
Bronchospasm	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Rhinitis allergic	1	(0.1)	1	0.05	5	(0.3)	9	0.64
Allergic bronchitis	0				1	(0.1)	1	0.05
Allergic cough	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

Hypersensitivity reactions (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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 disorders	1	(0.1)	1	0.05	0			
Lip swelling	1	(0.1)	1	0.05	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ01NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:11 - taesocpt/taesocpthypersenssumontt2dsas.txt

7.3.105 Hypersensitivity reactions (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Immune system disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Anaphylactic reaction	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Skin and subcutaneous tissue disorders	1	(0.0)	1	0.04	0			
Urticaria	1	(0.0)	1	0.04	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ01NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:13 - taesocpt/taessocpthypersenssumontp3asas.txt

7.3.106 Hypersensitivity reactions (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Immune system disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Anaphylactic reaction	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Skin and subcutaneous tissue disorders	1	(0.1)	1	0.05	0			
Urticaria	1	(0.1)	1	0.05	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ01NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:15 - taesocpt/taessocpthypersenssumontt2dsas.txt

7.3.107 Antibody formation leading to change in clinical effect (predefined MedDRA search) - on-treatment/ main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ04NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:08:02 - taesum/taeabformsumontp3asas.txt

7.3.108 Antibody formation leading to change in clinical effect (predefined MedDRA search) - on-treatment/ main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ04NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:08:04 - taesum/taeabformsumontt2dsas.txt

7.3.109 Antibody formation leading to change in clinical effect (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                                    CQ04NAM != "" & (ANL06FL) == "Y"
                                                  nn1436/nn1436-iss/submission_20221024_er
                                       05DEC2022:13:02:17 - taesocpt/taesocptabformsumontp3asas.txt
```

7.3.110 Antibody formation leading to change in clinical effect (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                                    CQ04NAM != "" & (ANL06FL) == "Y"
                                                  nn1436/nn1436-iss/submission_20221024_er
                                       05DEC2022:13:02:19 - taesocpt/taesocptabformsumontt2dsas.txt
```

7.3.111 Antibody formation leading to change in clinical effect (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ04NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                  nn1436/nn1436-iss/submission_20221024_er
                                       05DEC2022:13:02:21 - taesocpt/taessocptabformsumontp3asas.txt
```

7.3.112 Antibody formation leading to change in clinical effect (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ04NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                  nn1436/nn1436-iss/submission_20221024_er
                                       05DEC2022:13:02:23 - taesocpt/taessocptabformsumontt2dsas.txt
```

7.3.113 Rare events (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	91	(4.2)	104	6.35	86	(4.0)	101	5.76
Serious								
Yes	18	(0.8)	21	1.20	17	(0.8)	20	0.94
No	77	(3.5)	83	5.16	74	(3.4)	81	4.81
Missing	0				0			
Severity								
Severe	6	(0.3)	7	0.54	10	(0.5)	13	0.59
Moderate	24	(1.1)	25	1.38	22	(1.0)	26	1.52
Mild	65	(3.0)	72	4.43	58	(2.7)	62	3.65
Missing	0				0			
Related to basal insulin								
Probable	0				2	(0.1)	2	0.09
Possible	4	(0.2)	5	0.35	3	(0.1)	3	0.22
Unlikely	88	(4.1)	99	6.01	82	(3.8)	96	5.44
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				1	(0.0)	1	0.08
No	91	(4.2)	104	6.35	85	(3.9)	100	5.68
NA	0				0			
Missing	0				0			
Outcome								
Fatal	2	(0.1)	3	0.24	1	(0.0)	1	0.04
Not recovered/not resolved	44	(2.0)	49	3.05	48	(2.2)	54	3.14
Recovered/resolved with sequelae	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Recovering/resolving	6	(0.3)	6	0.34	2	(0.1)	2	0.12
Recovered/resolved	41	(1.9)	44	2.63	36	(1.7)	42	2.35
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.114 Rare events (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	77	(4.1)	90	5.81	79	(4.2)	94	5.89
Serious								
Yes	18	(1.0)	21	1.38	17	(0.9)	20	1.09
No	63	(3.4)	69	4.43	67	(3.6)	74	4.81
Missing	0				0			
Severity								
Severe	5	(0.3)	6	0.51	10	(0.5)	13	0.68
Moderate	21	(1.1)	22	1.27	20	(1.1)	24	1.54
Mild	55	(2.9)	62	4.03	53	(2.8)	57	3.67
Missing	0				0			
Related to basal insulin								
Probable	0				2	(0.1)	2	0.11
Possible	3	(0.2)	4	0.29	2	(0.1)	2	0.15
Unlikely	75	(4.0)	86	5.52	76	(4.0)	90	5.64
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				1	(0.1)	1	0.09
No	77	(4.1)	90	5.81	78	(4.2)	93	5.80
NA	0				0			
Missing	0				0			
Outcome								
Fatal	2	(0.1)	3	0.28	1	(0.1)	1	0.05
Not recovered/not resolved	35	(1.9)	40	2.55	45	(2.4)	51	3.31
Recovered/resolved with sequelae	2	(0.1)	2	0.11	2	(0.1)	2	0.11
Recovering/resolving	6	(0.3)	6	0.40	2	(0.1)	2	0.14
Recovered/resolved	36	(1.9)	39	2.49	32	(1.7)	38	2.29
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.115 Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	91	(4.2)	104	6.35	86	(4.0)	101	5.76
Cardiac disorders	45	(2.1)	50	2.88	46	(2.1)	52	2.89
Atrial fibrillation	13	(0.6)	14	0.73	6	(0.3)	6	0.31
Ventricular extrasystoles	8	(0.4)	8	0.52	2	(0.1)	3	0.14
Palpitations	7	(0.3)	7	0.40	7	(0.3)	7	0.45
Supraventricular extrasystoles	3	(0.1)	3	0.20	2	(0.1)	2	0.09
Tachycardia	3	(0.1)	3	0.13	7	(0.3)	7	0.42
Bundle branch block right	2	(0.1)	2	0.14	7	(0.3)	8	0.48
Supraventricular tachycardia	2	(0.1)	2	0.12	0			
Atrioventricular block first degree	2	(0.1)	2	0.12	0			
Bundle branch block left	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Arrhythmia	2	(0.1)	2	0.09	3	(0.1)	3	0.17
Cardiac flutter	1	(0.0)	1	0.08	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Atrial flutter	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Bradycardia	1	(0.0)	1	0.05	2	(0.1)	2	0.13
Sinus tachycardia	1	(0.0)	1	0.05	3	(0.1)	3	0.14
Sinus bradycardia	0				3	(0.1)	3	0.17
Cardiac arrest	0				2	(0.1)	2	0.09
Ventricular arrhythmia	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrioventricular block complete	0				1	(0.0)	1	0.05
Sinus arrhythmia	0				1	(0.0)	1	0.05
Hepatobiliary disorders	13	(0.6)	14	0.87	16	(0.7)	16	0.95
Hepatic steatosis	11	(0.5)	11	0.69	10	(0.5)	10	0.60
Hepatic calcification	1	(0.0)	1	0.09	0			
Liver disorder	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Non-alcoholic steatohepatitis	1	(0.0)	1	0.05	0			
Nonalcoholic fatty liver disease	0				2	(0.1)	2	0.09
Hepatic cirrhosis	0				2	(0.1)	2	0.13
Steatohepatitis	0				1	(0.0)	1	0.05
Renal and urinary disorders	10	(0.5)	10	0.69	9	(0.4)	10	0.49
Renal impairment	4	(0.2)	4	0.25	3	(0.1)	3	0.14
Acute kidney injury	3	(0.1)	3	0.20	5	(0.2)	5	0.22
Hydronephrosis	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Nephrotic syndrome	1	(0.0)	1	0.08	0			
Renal failure	1	(0.0)	1	0.08	0			
Urinary tract obstruction	0				1	(0.0)	1	0.05
Nervous system disorders	8	(0.4)	8	0.50	3	(0.1)	3	0.18
Syncope	7	(0.3)	7	0.41	1	(0.0)	1	0.05
Loss of consciousness	1	(0.0)	1	0.09	2	(0.1)	2	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	6	(0.3)	6	0.41	5	(0.2)	5	0.26
Type V hyperlipidaemia	3	(0.1)	3	0.20	1	(0.0)	1	0.08
Cystic fibrosis lung	1	(0.0)	1	0.08	0			
Corneal dystrophy	1	(0.0)	1	0.08	0			
Hydrocele	1	(0.0)	1	0.05	0			
Atrial septal defect	0				1	(0.0)	1	0.04
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Myotonic dystrophy	0				1	(0.0)	1	0.04
Congenital syphilitic osteochondritis	0				1	(0.0)	1	0.05
Investigations	4	(0.2)	4	0.31	8	(0.4)	8	0.58
Electrocardiogram abnormal	2	(0.1)	2	0.14	2	(0.1)	2	0.12
Heart rate increased	1	(0.0)	1	0.09	0			
Monocyte count decreased	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Platelet count decreased	0				3	(0.1)	3	0.24
Electrocardiogram repolarisation abnormality	0				1	(0.0)	1	0.05
White blood cell count decreased	0				1	(0.0)	1	0.09
Respiratory, thoracic and mediastinal disorders	4	(0.2)	5	0.27	0			
Pulmonary fibrosis	2	(0.1)	3	0.17	0			
Interstitial lung disease	2	(0.1)	2	0.09	0			
Blood and lymphatic system disorders	2	(0.1)	2	0.13	2	(0.1)	2	0.14
Leukopenia	1	(0.0)	1	0.08	0			
Thrombocytopenia	1	(0.0)	1	0.05	1	(0.0)	1	0.09
Pancytopenia	0				1	(0.0)	1	0.04
Gastrointestinal disorders	2	(0.1)	2	0.13	4	(0.2)	4	0.22
Pancreatitis chronic	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Pancreatitis	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Pancreatitis acute	0				1	(0.0)	1	0.05
Pancreatic pseudocyst	0				1	(0.0)	1	0.08
Infections and infestations	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Clostridium difficile colitis	1	(0.0)	1	0.04	0			
Clostridium difficile infection	1	(0.0)	1	0.04	1	(0.0)	1	0.05
General disorders and administration site conditions	1	(0.0)	1	0.08	0			
Multiple organ dysfunction syndrome	1	(0.0)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.116 Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	77	(4.1)	90	5.81	79	(4.2)	94	5.89
Cardiac disorders	39	(2.1)	44	2.67	43	(2.3)	49	3.02
Atrial fibrillation	12	(0.6)	13	0.73	6	(0.3)	6	0.36
Palpitations	6	(0.3)	6	0.36	5	(0.3)	5	0.31
Ventricular extrasystoles	5	(0.3)	5	0.27	2	(0.1)	3	0.16
Supraventricular extrasystoles	3	(0.2)	3	0.24	2	(0.1)	2	0.11
Tachycardia	3	(0.2)	3	0.15	7	(0.4)	7	0.48
Supraventricular tachycardia	2	(0.1)	2	0.14	0			
Atrioventricular block first degree	2	(0.1)	2	0.14	0			
Bundle branch block left	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Arrhythmia	2	(0.1)	2	0.10	3	(0.2)	3	0.20
Cardiac flutter	1	(0.1)	1	0.09	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Atrial flutter	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Bradycardia	1	(0.1)	1	0.05	2	(0.1)	2	0.15
Bundle branch block right	1	(0.1)	1	0.05	6	(0.3)	7	0.45
Sinus tachycardia	1	(0.1)	1	0.05	3	(0.2)	3	0.16
Sinus bradycardia	0				3	(0.2)	3	0.20
Cardiac arrest	0				2	(0.1)	2	0.10
Ventricular arrhythmia	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrioventricular block complete	0				1	(0.1)	1	0.05
Sinus arrhythmia	0				1	(0.1)	1	0.05
Renal and urinary disorders	10	(0.5)	10	0.80	9	(0.5)	10	0.56
Renal impairment	4	(0.2)	4	0.29	3	(0.2)	3	0.16
Acute kidney injury	3	(0.2)	3	0.24	5	(0.3)	5	0.26
Hydronephrosis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Nephrotic syndrome	1	(0.1)	1	0.09	0			
Renal failure	1	(0.1)	1	0.09	0			
Urinary tract obstruction	0				1	(0.1)	1	0.05
Hepatobiliary disorders	9	(0.5)	10	0.57	15	(0.8)	15	0.99
Hepatic steatosis	8	(0.4)	8	0.47	9	(0.5)	9	0.59
Liver disorder	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Non-alcoholic steatohepatitis	1	(0.1)	1	0.05	0			
Nonalcoholic fatty liver disease	0				2	(0.1)	2	0.11
Hepatic cirrhosis	0				2	(0.1)	2	0.15
Steatohepatitis	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	6	(0.3)	6	0.47	5	(0.3)	5	0.30
Type V hyperlipidaemia	3	(0.2)	3	0.24	1	(0.1)	1	0.09
Cystic fibrosis lung	1	(0.1)	1	0.09	0			
Corneal dystrophy	1	(0.1)	1	0.09	0			
Hydrocele	1	(0.1)	1	0.05	0			
Atrial septal defect	0				1	(0.1)	1	0.05
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05
Myotonic dystrophy	0				1	(0.1)	1	0.05
Congenital syphilitic osteochondritis	0				1	(0.1)	1	0.05
Nervous system disorders	6	(0.3)	6	0.36	2	(0.1)	2	0.11
Syncope	6	(0.3)	6	0.36	1	(0.1)	1	0.05
Loss of consciousness	0				1	(0.1)	1	0.05
Respiratory, thoracic and mediastinal disorders	4	(0.2)	5	0.31	0			
Pulmonary fibrosis	2	(0.1)	3	0.20	0			
Interstitial lung disease	2	(0.1)	2	0.11	0			
Blood and lymphatic system disorders	2	(0.1)	2	0.15	1	(0.1)	1	0.05
Leukopenia	1	(0.1)	1	0.09	0			
Thrombocytopenia	1	(0.1)	1	0.05	0			
Pancytopenia	0				1	(0.1)	1	0.05
Gastrointestinal disorders	2	(0.1)	2	0.15	4	(0.2)	4	0.25
Pancreatitis chronic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Pancreatitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Pancreatitis acute	0				1	(0.1)	1	0.05
Pancreatic pseudocyst	0				1	(0.1)	1	0.09
Investigations	2	(0.1)	2	0.14	7	(0.4)	7	0.56
Monocyte count decreased	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Electrocardiogram abnormal	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Platelet count decreased	0				3	(0.2)	3	0.28
Electrocardiogram repolarisation abnormality	0				1	(0.1)	1	0.05
Infections and infestations	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Clostridium difficile colitis	1	(0.1)	1	0.05	0			
Clostridium difficile infection	1	(0.1)	1	0.05	1	(0.1)	1	0.05
General disorders and administration site conditions	1	(0.1)	1	0.09	0			
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.117 Rare events (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	18	(0.8)	21	1.20	17	(0.8)	20	0.94
Cardiac disorders	11	(0.5)	13	0.66	7	(0.3)	8	0.36
Atrial fibrillation	6	(0.3)	6	0.28	2	(0.1)	2	0.09
Supraventricular tachycardia	2	(0.1)	2	0.12	0			
Arrhythmia	2	(0.1)	2	0.09	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Atrial flutter	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Sinus tachycardia	1	(0.0)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.09
Palpitations	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrioventricular block complete	0				1	(0.0)	1	0.05
Renal and urinary disorders	3	(0.1)	3	0.24	5	(0.2)	5	0.23
Acute kidney injury	2	(0.1)	2	0.16	4	(0.2)	4	0.18
Renal failure	1	(0.0)	1	0.08	0			
Urinary tract obstruction	0				1	(0.0)	1	0.05
Nervous system disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Syncope	1	(0.0)	1	0.08	0			
Loss of consciousness	0				1	(0.0)	1	0.04
General disorders and administration site conditions	1	(0.0)	1	0.08	0			
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Congenital, familial and genetic disorders	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Hydrocele	1	(0.0)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.05	0			
Interstitial lung disease	1	(0.0)	1	0.05	0			
Infections and infestations	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Clostridium difficile colitis	1	(0.0)	1	0.04	0			
Clostridium difficile infection	0				1	(0.0)	1	0.05
Gastrointestinal disorders	0				2	(0.1)	2	0.13
Pancreatitis acute	0				1	(0.0)	1	0.05
Pancreatic pseudocyst	0				1	(0.0)	1	0.08
Blood and lymphatic system disorders	0				1	(0.0)	1	0.04
Pancytopenia	0				1	(0.0)	1	0.04
Hepatobiliary disorders	0				1	(0.0)	1	0.05
Hepatic cirrhosis	0				1	(0.0)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.118 Rare events (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	18	(1.0)	21	1.38	17	(0.9)	20	1.09
Cardiac disorders	11	(0.6)	13	0.76	7	(0.4)	8	0.42
Atrial fibrillation	6	(0.3)	6	0.32	2	(0.1)	2	0.11
Supraventricular tachycardia	2	(0.1)	2	0.14	0			
Arrhythmia	2	(0.1)	2	0.10	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Atrial flutter	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Sinus tachycardia	1	(0.1)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.10
Palpitations	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrioventricular block complete	0				1	(0.1)	1	0.05
Renal and urinary disorders	3	(0.2)	3	0.28	5	(0.3)	5	0.26
Acute kidney injury	2	(0.1)	2	0.18	4	(0.2)	4	0.21
Renal failure	1	(0.1)	1	0.09	0			
Urinary tract obstruction	0				1	(0.1)	1	0.05
Nervous system disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Syncope	1	(0.1)	1	0.09	0			
Loss of consciousness	0				1	(0.1)	1	0.05
General disorders and administration site conditions	1	(0.1)	1	0.09	0			
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Congenital, familial and genetic disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Hydrocele	1	(0.1)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.05	0			
Interstitial lung disease	1	(0.1)	1	0.05	0			
Infections and infestations	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Clostridium difficile colitis	1	(0.1)	1	0.05	0			
Clostridium difficile infection	0				1	(0.1)	1	0.05
Gastrointestinal disorders	0				2	(0.1)	2	0.15
Pancreatitis acute	0				1	(0.1)	1	0.05
Pancreatic pseudocyst	0				1	(0.1)	1	0.09
Blood and lymphatic system disorders	0				1	(0.1)	1	0.05
Pancytopenia	0				1	(0.1)	1	0.05
Hepatobiliary disorders	0				1	(0.1)	1	0.05
Hepatic cirrhosis	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.119 Rare events (predefined MedDRA search) - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	91	(4.2)	104	6.28	87	(4.0)	103	5.84
Serious								
Yes	18	(0.8)	21	1.18	17	(0.8)	20	0.93
No	77	(3.5)	83	5.10	75	(3.5)	83	4.91
Missing	0				0			
Severity								
Severe	6	(0.3)	7	0.53	10	(0.5)	13	0.58
Moderate	24	(1.1)	25	1.37	22	(1.0)	26	1.50
Mild	65	(3.0)	72	4.39	59	(2.7)	64	3.76
Missing	0				0			
Related to basal insulin								
Probable	0				2	(0.1)	2	0.09
Possible	4	(0.2)	5	0.34	3	(0.1)	3	0.22
Unlikely	88	(4.1)	99	5.94	83	(3.8)	98	5.53
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				1	(0.0)	1	0.08
No	91	(4.2)	104	6.28	86	(4.0)	102	5.76
NA	0				0			
Missing	0				0			
Outcome								
Fatal	2	(0.1)	3	0.24	1	(0.0)	1	0.04
Not recovered/not resolved	44	(2.0)	49	3.02	49	(2.3)	56	3.26
Recovered/resolved with sequelae	2	(0.1)	2	0.09	2	(0.1)	2	0.09
Recovering/resolving	6	(0.3)	6	0.34	2	(0.1)	2	0.12
Recovered/resolved	41	(1.9)	44	2.60	36	(1.7)	42	2.33
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.120 Rare events (predefined MedDRA search) - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	77	(4.1)	90	5.74	80	(4.3)	96	6.00
Serious								
Yes	18	(1.0)	21	1.36	17	(0.9)	20	1.07
No	63	(3.4)	69	4.38	68	(3.6)	76	4.92
Missing	0				0			
Severity								
Severe	5	(0.3)	6	0.50	10	(0.5)	13	0.67
Moderate	21	(1.1)	22	1.25	20	(1.1)	24	1.52
Mild	55	(2.9)	62	3.99	54	(2.9)	59	3.81
Missing	0				0			
Related to basal insulin								
Probable	0				2	(0.1)	2	0.11
Possible	3	(0.2)	4	0.29	2	(0.1)	2	0.14
Unlikely	75	(4.0)	86	5.46	77	(4.1)	92	5.75
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	0				1	(0.1)	1	0.09
No	77	(4.1)	90	5.74	79	(4.2)	95	5.91
NA	0				0			
Missing	0				0			
Outcome								
Fatal	2	(0.1)	3	0.27	1	(0.1)	1	0.05
Not recovered/not resolved	35	(1.9)	40	2.52	46	(2.5)	53	3.44
Recovered/resolved with sequelae	2	(0.1)	2	0.10	2	(0.1)	2	0.10
Recovering/resolving	6	(0.3)	6	0.39	2	(0.1)	2	0.14
Recovered/resolved	36	(1.9)	39	2.46	32	(1.7)	38	2.26
Unknown	0				0			
Missing	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.121 Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	91	(4.2)	104	6.28	87	(4.0)	103	5.84
Cardiac disorders	45	(2.1)	50	2.85	47	(2.2)	53	2.94
Atrial fibrillation	13	(0.6)	14	0.72	6	(0.3)	6	0.31
Ventricular extrasystoles	8	(0.4)	8	0.51	2	(0.1)	3	0.13
Palpitations	7	(0.3)	7	0.40	7	(0.3)	7	0.45
Supraventricular extrasystoles	3	(0.1)	3	0.20	2	(0.1)	2	0.09
Tachycardia	3	(0.1)	3	0.13	7	(0.3)	7	0.41
Bundle branch block right	2	(0.1)	2	0.14	7	(0.3)	8	0.48
Supraventricular tachycardia	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Atrioventricular block first degree	2	(0.1)	2	0.12	0			
Bundle branch block left	2	(0.1)	2	0.12	1	(0.0)	1	0.08
Arrhythmia	2	(0.1)	2	0.09	3	(0.1)	3	0.17
Cardiac flutter	1	(0.0)	1	0.08	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Atrial flutter	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Bradycardia	1	(0.0)	1	0.05	2	(0.1)	2	0.12
Sinus tachycardia	1	(0.0)	1	0.05	3	(0.1)	3	0.13
Sinus bradycardia	0				3	(0.1)	3	0.17
Cardiac arrest	0				2	(0.1)	2	0.09
Ventricular arrhythmia	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrioventricular block complete	0				1	(0.0)	1	0.05
Sinus arrhythmia	0				1	(0.0)	1	0.05
Hepatobiliary disorders	13	(0.6)	14	0.87	16	(0.7)	16	0.93
Hepatic steatosis	11	(0.5)	11	0.68	10	(0.5)	10	0.59
Hepatic calcification	1	(0.0)	1	0.09	0			
Liver disorder	1	(0.0)	1	0.05	1	(0.0)	1	0.08
Non-alcoholic steatohepatitis	1	(0.0)	1	0.05	0			
Nonalcoholic fatty liver disease	0				2	(0.1)	2	0.09
Hepatic cirrhosis	0				2	(0.1)	2	0.12
Steatohepatitis	0				1	(0.0)	1	0.05
Renal and urinary disorders	10	(0.5)	10	0.68	9	(0.4)	10	0.48
Renal impairment	4	(0.2)	4	0.25	3	(0.1)	3	0.14
Acute kidney injury	3	(0.1)	3	0.20	5	(0.2)	5	0.22
Hydronephrosis	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Nephrotic syndrome	1	(0.0)	1	0.08	0			
Renal failure	1	(0.0)	1	0.08	0			
Urinary tract obstruction	0				1	(0.0)	1	0.05
Nervous system disorders	8	(0.4)	8	0.50	3	(0.1)	3	0.18
Syncope	7	(0.3)	7	0.40	1	(0.0)	1	0.05
Loss of consciousness	1	(0.0)	1	0.09	2	(0.1)	2	0.14

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - 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	6	(0.3)	6	0.41	5	(0.2)	5	0.26
Type V hyperlipidaemia	3	(0.1)	3	0.20	1	(0.0)	1	0.08
Cystic fibrosis lung	1	(0.0)	1	0.08	0			
Corneal dystrophy	1	(0.0)	1	0.08	0			
Hydrocele	1	(0.0)	1	0.05	0			
Atrial septal defect	0				1	(0.0)	1	0.04
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Myotonic dystrophy	0				1	(0.0)	1	0.04
Congenital syphilitic osteochondritis	0				1	(0.0)	1	0.05
Investigations	4	(0.2)	4	0.31	9	(0.4)	9	0.65
Electrocardiogram abnormal	2	(0.1)	2	0.14	2	(0.1)	2	0.12
Heart rate increased	1	(0.0)	1	0.09	0			
Monocyte count decreased	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Platelet count decreased	0				3	(0.1)	3	0.23
Electrocardiogram repolarisation abnormality	0				1	(0.0)	1	0.05
Electrocardiogram P wave abnormal	0				1	(0.0)	1	0.08
White blood cell count decreased	0				1	(0.0)	1	0.09
Respiratory, thoracic and mediastinal disorders	4	(0.2)	5	0.26	0			
Pulmonary fibrosis	2	(0.1)	3	0.17	0			
Interstitial lung disease	2	(0.1)	2	0.09	0			
Blood and lymphatic system disorders	2	(0.1)	2	0.12	2	(0.1)	2	0.14
Leukopenia	1	(0.0)	1	0.08	0			
Thrombocytopenia	1	(0.0)	1	0.05	1	(0.0)	1	0.09
Pancytopenia	0				1	(0.0)	1	0.04
Gastrointestinal disorders	2	(0.1)	2	0.13	4	(0.2)	4	0.22
Pancreatitis chronic	1	(0.0)	1	0.08	1	(0.0)	1	0.05
Pancreatitis	1	(0.0)	1	0.05	1	(0.0)	1	0.05
Pancreatitis acute	0				1	(0.0)	1	0.05
Pancreatic pseudocyst	0				1	(0.0)	1	0.08
Infections and infestations	2	(0.1)	2	0.09	1	(0.0)	1	0.05
Clostridium difficile colitis	1	(0.0)	1	0.04	0			
Clostridium difficile infection	1	(0.0)	1	0.04	1	(0.0)	1	0.05
General disorders and administration site conditions	1	(0.0)	1	0.08	0			
Multiple organ dysfunction syndrome	1	(0.0)	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, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.122 Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	77	(4.1)	90	5.74	80	(4.3)	96	6.00
Cardiac disorders	39	(2.1)	44	2.64	44	(2.3)	50	3.07
Atrial fibrillation	12	(0.6)	13	0.72	6	(0.3)	6	0.36
Palpitations	6	(0.3)	6	0.35	5	(0.3)	5	0.30
Ventricular extrasystoles	5	(0.3)	5	0.27	2	(0.1)	3	0.15
Supraventricular extrasystoles	3	(0.2)	3	0.23	2	(0.1)	2	0.10
Tachycardia	3	(0.2)	3	0.15	7	(0.4)	7	0.48
Supraventricular tachycardia	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Atrioventricular block first degree	2	(0.1)	2	0.14	0			
Bundle branch block left	2	(0.1)	2	0.14	1	(0.1)	1	0.09
Arrhythmia	2	(0.1)	2	0.10	3	(0.2)	3	0.20
Cardiac flutter	1	(0.1)	1	0.09	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Atrial flutter	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Bradycardia	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Bundle branch block right	1	(0.1)	1	0.05	6	(0.3)	7	0.44
Sinus tachycardia	1	(0.1)	1	0.05	3	(0.2)	3	0.15
Sinus bradycardia	0				3	(0.2)	3	0.20
Cardiac arrest	0				2	(0.1)	2	0.10
Ventricular arrhythmia	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrioventricular block complete	0				1	(0.1)	1	0.05
Sinus arrhythmia	0				1	(0.1)	1	0.05
Renal and urinary disorders	10	(0.5)	10	0.79	9	(0.5)	10	0.56
Renal impairment	4	(0.2)	4	0.29	3	(0.2)	3	0.16
Acute kidney injury	3	(0.2)	3	0.23	5	(0.3)	5	0.26
Hydronephrosis	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Nephrotic syndrome	1	(0.1)	1	0.09	0			
Renal failure	1	(0.1)	1	0.09	0			
Urinary tract obstruction	0				1	(0.1)	1	0.05
Hepatobiliary disorders	9	(0.5)	10	0.57	15	(0.8)	15	0.97
Hepatic steatosis	8	(0.4)	8	0.46	9	(0.5)	9	0.58
Liver disorder	1	(0.1)	1	0.05	1	(0.1)	1	0.09
Non-alcoholic steatohepatitis	1	(0.1)	1	0.05	0			
Nonalcoholic fatty liver disease	0				2	(0.1)	2	0.10
Hepatic cirrhosis	0				2	(0.1)	2	0.14
Steatohepatitis	0				1	(0.1)	1	0.05
Congenital, familial and genetic disorders	6	(0.3)	6	0.47	5	(0.3)	5	0.29
Type V hyperlipidaemia	3	(0.2)	3	0.23	1	(0.1)	1	0.09
Cystic fibrosis lung	1	(0.1)	1	0.09	0			
Corneal dystrophy	1	(0.1)	1	0.09	0			
Hydrocele	1	(0.1)	1	0.05	0			
Atrial septal defect	0				1	(0.1)	1	0.05
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05
Myotonic dystrophy	0				1	(0.1)	1	0.05
Congenital syphilitic osteochondritis	0				1	(0.1)	1	0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

Rare events (predefined MedDRA search) - adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Nervous system disorders	6	(0.3)	6	0.36	2	(0.1)	2	0.10
Syncope	6	(0.3)	6	0.36	1	(0.1)	1	0.05
Loss of consciousness	0				1	(0.1)	1	0.05
Respiratory, thoracic and mediastinal disorders	4	(0.2)	5	0.31	0			
Pulmonary fibrosis	2	(0.1)	3	0.20	0			
Interstitial lung disease	2	(0.1)	2	0.11	0			
Blood and lymphatic system disorders	2	(0.1)	2	0.14	1	(0.1)	1	0.05
Leukopenia	1	(0.1)	1	0.09	0			
Thrombocytopenia	1	(0.1)	1	0.05	0			
Pancytopenia	0				1	(0.1)	1	0.05
Gastrointestinal disorders	2	(0.1)	2	0.14	4	(0.2)	4	0.25
Pancreatitis chronic	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Pancreatitis	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Pancreatitis acute	0				1	(0.1)	1	0.05
Pancreatic pseudocyst	0				1	(0.1)	1	0.09
Investigations	2	(0.1)	2	0.14	8	(0.4)	8	0.65
Monocyte count decreased	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Electrocardiogram abnormal	1	(0.1)	1	0.05	2	(0.1)	2	0.14
Platelet count decreased	0				3	(0.2)	3	0.27
Electrocardiogram repolarisation abnormality	0				1	(0.1)	1	0.05
Electrocardiogram P wave abnormal	0				1	(0.1)	1	0.09
Infections and infestations	2	(0.1)	2	0.10	1	(0.1)	1	0.05
Clostridium difficile colitis	1	(0.1)	1	0.05	0			
Clostridium difficile infection	1	(0.1)	1	0.05	1	(0.1)	1	0.05
General disorders and administration site conditions	1	(0.1)	1	0.09	0			
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.123 Rare events (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - 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	2170				2170			
PYO (years)	1707.11				1702.14			
Events	18	(0.8)	21	1.18	17	(0.8)	20	0.93
Cardiac disorders	11	(0.5)	13	0.65	7	(0.3)	8	0.36
Atrial fibrillation	6	(0.3)	6	0.28	2	(0.1)	2	0.09
Supraventricular tachycardia	2	(0.1)	2	0.12	0			
Arrhythmia	2	(0.1)	2	0.09	0			
Cardio-respiratory arrest	1	(0.0)	1	0.08	0			
Atrial flutter	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Sinus tachycardia	1	(0.0)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.09
Palpitations	0				1	(0.0)	1	0.04
Ventricular tachycardia	0				1	(0.0)	1	0.04
Atrioventricular block complete	0				1	(0.0)	1	0.05
Renal and urinary disorders	3	(0.1)	3	0.23	5	(0.2)	5	0.22
Acute kidney injury	2	(0.1)	2	0.16	4	(0.2)	4	0.18
Renal failure	1	(0.0)	1	0.08	0			
Urinary tract obstruction	0				1	(0.0)	1	0.05
Nervous system disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Syncope	1	(0.0)	1	0.08	0			
Loss of consciousness	0				1	(0.0)	1	0.04
General disorders and administration site conditions	1	(0.0)	1	0.08	0			
Multiple organ dysfunction syndrome	1	(0.0)	1	0.08	0			
Congenital, familial and genetic disorders	1	(0.0)	1	0.05	1	(0.0)	1	0.04
Hydrocele	1	(0.0)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.0)	1	0.04
Respiratory, thoracic and mediastinal disorders	1	(0.0)	1	0.05	0			
Interstitial lung disease	1	(0.0)	1	0.05	0			
Infections and infestations	1	(0.0)	1	0.04	1	(0.0)	1	0.05
Clostridium difficile colitis	1	(0.0)	1	0.04	0			
Clostridium difficile infection	0				1	(0.0)	1	0.05
Gastrointestinal disorders	0				2	(0.1)	2	0.12
Pancreatitis acute	0				1	(0.0)	1	0.05
Pancreatic pseudocyst	0				1	(0.0)	1	0.08
Blood and lymphatic system disorders	0				1	(0.0)	1	0.04
Pancytopenia	0				1	(0.0)	1	0.04
Hepatobiliary disorders	0				1	(0.0)	1	0.05
Hepatic cirrhosis	0				1	(0.0)	1	0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO). Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.124 Rare events (predefined MedDRA search) - serious adverse events by system organ class and preferred term - in-trial - summary - safety analysis set - T2D pool

	Insulin icodec				Daily basal insulin			
	N	(Adj.%)	E	Adj.R	N	(Adj.%)	E	Adj.R
Number of subjects	1880				1878			
PYO (years)	1563.87				1557.45			
Events	18	(1.0)	21	1.36	17	(0.9)	20	1.07
Cardiac disorders	11	(0.6)	13	0.75	7	(0.4)	8	0.41
Atrial fibrillation	6	(0.3)	6	0.32	2	(0.1)	2	0.11
Supraventricular tachycardia	2	(0.1)	2	0.14	0			
Arrhythmia	2	(0.1)	2	0.10	0			
Cardio-respiratory arrest	1	(0.1)	1	0.09	0			
Atrial flutter	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Sinus tachycardia	1	(0.1)	1	0.05	0			
Cardiac arrest	0				2	(0.1)	2	0.10
Palpitations	0				1	(0.1)	1	0.05
Ventricular tachycardia	0				1	(0.1)	1	0.05
Atrioventricular block complete	0				1	(0.1)	1	0.05
Renal and urinary disorders	3	(0.2)	3	0.27	5	(0.3)	5	0.26
Acute kidney injury	2	(0.1)	2	0.18	4	(0.2)	4	0.20
Renal failure	1	(0.1)	1	0.09	0			
Urinary tract obstruction	0				1	(0.1)	1	0.05
Nervous system disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Syncope	1	(0.1)	1	0.09	0			
Loss of consciousness	0				1	(0.1)	1	0.05
General disorders and administration site conditions	1	(0.1)	1	0.09	0			
Multiple organ dysfunction syndrome	1	(0.1)	1	0.09	0			
Congenital, familial and genetic disorders	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Hydrocele	1	(0.1)	1	0.05	0			
Hypertrophic cardiomyopathy	0				1	(0.1)	1	0.05
Respiratory, thoracic and mediastinal disorders	1	(0.1)	1	0.05	0			
Interstitial lung disease	1	(0.1)	1	0.05	0			
Infections and infestations	1	(0.1)	1	0.05	1	(0.1)	1	0.05
Clostridium difficile colitis	1	(0.1)	1	0.05	0			
Clostridium difficile infection	0				1	(0.1)	1	0.05
Gastrointestinal disorders	0				2	(0.1)	2	0.14
Pancreatitis acute	0				1	(0.1)	1	0.05
Pancreatic pseudocyst	0				1	(0.1)	1	0.09
Blood and lymphatic system disorders	0				1	(0.1)	1	0.05
Pancytopenia	0				1	(0.1)	1	0.05
Hepatobiliary disorders	0				1	(0.1)	1	0.05
Hepatic cirrhosis	0				1	(0.1)	1	0.05

%: Percentage of subjects with one or more events, E: Number of adverse events, N: Number of subjects with one or more events, PYO: Patient years of observation (1 PYO = 365.25 days), R: Rate (number of adverse events per 100 PYO), Adj.: Adjusted percentages and rates were calculated using the Cochran-Mantel-Haenszel method to account for differences between trials. In-trial: Onset date on or after the day of randomisation and no later than the last subject-site contact or withdrawal/ death date for subjects that withdraws/dies. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. T2D pool: ONWARDS 1-5, only main part of ONWARDS 1. T2D: Type 2 diabetes. MedDRA version 24.1. Events found via MedDRA queries.

7.3.125 Suspected transmission of an infectious agent via a trial product (predefined MedDRA search) - on- treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ06NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:08:14 - taesum/taeinfagtsumontp3asas.txt

7.3.126 Suspected transmission of an infectious agent via a trial product (predefined MedDRA search) - on- treatment/main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AESER ASEV AREL1 ATECH1 AOUT; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ06NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:08:16 - taesum/taeinfagtsumontt2dsas.txt

7.3.127 Suspected transmission of an infectious agent via a trial product (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ06NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:44 - taesocpt/taesocptinfagtsumontp3asas.txt

7.3.128 Suspected transmission of an infectious agent via a trial product (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

There is no data for this output

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ06NAM != "" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:46 - taesocpt/taesocptinfagtsumontt2dsas.txt

7.3.129 Suspected transmission of an infectious agent via a trial product (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - phase 3a pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ06NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                        05DEC2022:13:02:47 - taesocpt/taessocptinfagtsumontp3asas.txt
```

7.3.130 Suspected transmission of an infectious agent via a trial product (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-on-treatment - summary - safety analysis set - T2D pool

```
There is no data for this output
```

```
                              adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
 adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" &
                                                     CQ06NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
                                                          nn1436/nn1436-iss/submission_20221024_er
                                        05DEC2022:13:02:49 - taesocpt/taessocptinfagtsumontt2dsas.txt
```

7.3.131 Medication errors incl. misuse and abuse (predefined MedDRA search) - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	37	(1.7)	40	3.34	31	(1.4)	36	2.77
Serious								
Yes	1	(0.0)	1	0.09	2	(0.1)	2	0.16
No	36	(1.7)	39	3.24	29	(1.3)	34	2.61
Missing	0				0			
Severity								
Severe	1	(0.0)	1	0.09	0			
Moderate	10	(0.5)	10	0.85	6	(0.3)	6	0.47
Mild	27	(1.2)	29	2.40	25	(1.2)	30	2.30
Missing	0				0			
Related to basal insulin								
Probable	18	(0.8)	19	1.60	4	(0.2)	5	0.40
Possible	4	(0.2)	4	0.30	0			
Unlikely	16	(0.7)	17	1.44	27	(1.2)	31	2.37
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.0)	1	0.08	1	(0.0)	1	0.08
No	36	(1.7)	39	3.26	30	(1.4)	35	2.69
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	0				1	(0.0)	1	0.04
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	37	(1.7)	40	3.34	30	(1.4)	35	2.73
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.132 Medication errors incl. misuse and abuse (predefined MedDRA search) - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	21	(1.1)	22	1.90	26	(1.4)	30	2.56
Serious								
Yes	0				2	(0.1)	2	0.18
No	21	(1.1)	22	1.90	24	(1.3)	28	2.37
Missing	0				0			
Severity								
Severe	0				0			
Moderate	4	(0.2)	4	0.32	4	(0.2)	4	0.33
Mild	17	(0.9)	18	1.57	22	(1.2)	26	2.23
Missing	0				0			
Related to basal insulin								
Probable	8	(0.4)	8	0.65	4	(0.2)	5	0.46
Possible	3	(0.2)	3	0.23	0			
Unlikely	10	(0.5)	11	1.01	22	(1.2)	25	2.10
Missing	0				0			
Related to technical complaint for basal insulin								
Yes	1	(0.1)	1	0.09	1	(0.1)	1	0.09
No	20	(1.1)	21	1.80	25	(1.3)	29	2.47
NA	0				0			
Missing	0				0			
Outcome								
Fatal	0				0			
Not recovered/not resolved	0				1	(0.1)	1	0.05
Recovered/resolved with sequelae	0				0			
Recovering/resolving	0				0			
Recovered/resolved	21	(1.1)	22	1.90	25	(1.3)	29	2.51
Unknown	0				0			
Missing	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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.133 Medication errors incl. misuse and abuse (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	37	(1.7)	40	3.34	31	(1.4)	36	2.77
Injury, poisoning and procedural complications	36	(1.7)	39	3.26	30	(1.4)	35	2.73
Accidental overdose	14	(0.6)	15	1.24	4	(0.2)	5	0.41
Incorrect dose administered	6	(0.3)	6	0.52	5	(0.2)	7	0.52
Prescribed overdose	5	(0.2)	5	0.47	0			
Overdose	4	(0.2)	4	0.28	3	(0.1)	3	0.21
Medication error	2	(0.1)	2	0.16	3	(0.1)	3	0.25
Product administration error	1	(0.0)	1	0.09	2	(0.1)	2	0.12
Product dispensing error	1	(0.0)	1	0.09	0			
Underdose	1	(0.0)	1	0.08	5	(0.2)	5	0.36
Accidental underdose	1	(0.0)	1	0.08	0			
Extra dose administered	1	(0.0)	1	0.08	1	(0.0)	1	0.08
Wrong product administered	1	(0.0)	2	0.16	6	(0.3)	6	0.53
Wrong dose	0				2	(0.1)	2	0.16
Intentional overdose	0				1	(0.0)	1	0.08
Psychiatric disorders	1	(0.0)	1	0.08	1	(0.0)	1	0.04
Drug abuse	1	(0.0)	1	0.08	0			
Drug dependence	0				1	(0.0)	1	0.04

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.134 Medication errors incl. misuse and abuse (predefined MedDRA search) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	21	(1.1)	22	1.90	26	(1.4)	30	2.56
Injury, poisoning and procedural complications	20	(1.1)	21	1.80	25	(1.3)	29	2.51
Accidental overdose	7	(0.4)	7	0.56	3	(0.2)	4	0.37
Overdose	4	(0.2)	4	0.33	3	(0.2)	3	0.24
Incorrect dose administered	3	(0.2)	3	0.28	5	(0.3)	7	0.60
Medication error	2	(0.1)	2	0.18	2	(0.1)	2	0.18
Underdose	1	(0.1)	1	0.09	5	(0.3)	5	0.42
Accidental underdose	1	(0.1)	1	0.09	0			
Extra dose administered	1	(0.1)	1	0.09	1	(0.1)	1	0.09
Wrong product administered	1	(0.1)	2	0.19	2	(0.1)	2	0.18
Product administration error	0				2	(0.1)	2	0.14
Wrong dose	0				2	(0.1)	2	0.18
Intentional overdose	0				1	(0.1)	1	0.09
Psychiatric disorders	1	(0.1)	1	0.09	1	(0.1)	1	0.05
Drug abuse	1	(0.1)	1	0.09	0			
Drug dependence	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

7.3.135 Medication errors incl. misuse and abuse (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	1	(0.0)	1	0.09	2	(0.1)	2	0.16
Injury, poisoning and procedural complications	1	(0.0)	1	0.09	2	(0.1)	2	0.16
Product administration error	1	(0.0)	1	0.09	0			
Overdose	0				1	(0.0)	1	0.08
Accidental overdose	0				1	(0.0)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR2N == 2 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR2N == 2 & SAFFL == "Y" & (ANELFL) == "Y" & CQ03NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:56 - taesocpt/taessocptmederrsumontp3asas.txt

7.3.136 Medication errors incl. misuse and abuse (predefined MedDRA search) - serious adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	0	(0.0)	0	0.00	2	(0.1)	2	0.18
Injury, poisoning and procedural complications	0				2	(0.1)	2	0.18
Overdose	0				1	(0.1)	1	0.09
Accidental overdose	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & CQ03NAM != "" & AESER == "Y" & (ANL06FL) == "Y"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:13:02:58 - taesocpt/taessocptmederrsumontt2dsas.txt

7.3.137 Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
154001/ 4477/Ico/ 5[redacted]/Female/2[redacted]	4	Injection site hypersensitivity/ Hypersensitivity reaction at injection site/ 08JUN2021/176/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 08JUN2021/570 U	Yes: Itching; Burning; Pain/ Haematoma; Induration; Oedema/ No	1.0 in/ Flat skin
605003/ 4477/Ico/ 7[redacted]/Female/2[redacted]	3	Lipodystrophy acquired/ Area of **lipodystrophy in the right upper limb/ 22DEC2021/310/1	Non-serious/ Mild/ Recovering/resolving	Ico/ 16DEC2021/490 U	No/ Induration/ No	3.0 cm/ Flat skin
701005/ 4477/Ico/ 4[redacted]/Male/2[redacted]	2	Injection site reaction/ Injection site reaction- erythema and itching at injection site/ 17APR2021/ 17/2	Non-serious/ Moderate/ Recovered/resolved	Ico/ 15APR2021/110 U	Yes: Itching/ Erythema/ Other: Pt has sensitive skin	2.0 cm/ Flat skin
901002/ 4477/Ico/ 5[redacted]/Female/4[redacted]	1	Injection site erythema/ Red spot on the skin (abdominal area) at injection site/ 04MAY2021/ 16/5	Non-serious/ Mild/ Recovered/resolved	Ico/ 04MAY2021/110 U	Yes: Itching/ Erythema/ No	4.5 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:57:34 - linjreacform/linjreacform.txt

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
113004/ 4477/IGlar/ 6[redacted]/Female/3[redacted]	3	Injection site urticaria/ Small welt after injection/ 31JAN2022/340/1	Non-serious/ Mild/ Recovered/resolved	IGlar/ 31JAN2022/43 U	No/ Other: Other/ No	1.0 cm/ Flat skin
117004/ 4477/IGlar/ 4[redacted]/Male/2[redacted]	2	Injection site erythema/ Injection site reaction, redness/ 01JUL2021/ 84/69	Non-serious/ Moderate/ Recovered/resolved	IGlar/ 01JUL2021/0 U	No/ Thickening of the skin; Other: Other/ Other: The subject injected in the same spot every other day	1.5 in/ Flat skin
122001/ 4477/IGlar/ 6[redacted]/Female/3[redacted]	1	Injection site bruising/ Intermittent bruising at injection sites/ 06JAN2021/ 20/	Non-serious/ Mild/ Not recovered/not resolved	IGlar/ 06JAN2021/16 U	No/ Ecchymosis/ No	2.0 cm/ Skin fold
213008/ 4477/IGlar/ 7[redacted]/Female/3[redacted]	5	Injection site bruising/ Postinjection bruising/ 29JUN2021/ 86/34	Non-serious/ Mild/ Recovering/resolving	IGlar/ 29JUN2021/40 U	No/ Haemorrhage/ No	4.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
401013/ 4477/IGlar/ 4[redacted]/Male/3[redacted]	1	Injection site haemorrhage/ Administration site ecchymosis/ 25FEB2021/ 20/10	Non-serious/ Mild/ Recovered/resolved	IGlar/ 24FEB2021/16 U	No/ Ecchymosis/ No	0.2 cm/ Flat skin
	1	Injection site haemorrhage/ Administration site ecchymosis/ 25FEB2021/ 20/10	Non-serious/ Mild/ Recovered/resolved	IGlar/ 25FEB2021/16 U	No/ Ecchymosis/ No	0.2 cm/ Flat skin
407007/ 4477/IGlar/ 4[redacted]/Male/2[redacted]	6	Injection site hypertrophy/ Injection site hypertrophy/ 29OCT2021/281/85	Non-serious/ Mild/ Recovered/resolved	IGlar/ 29OCT2021/54 U	No/ Induration/ No	7.0 cm/ Flat skin
407011/ 4477/IGlar/ 6[redacted]/Male/2[redacted]	3	Injection site erythema/ Injection site reaction(erythema)/ 14JUN2021/134/12	Non-serious/ Mild/ Recovered/resolved	IGlar/ 14JUN2021/25 U	Yes: Itching/ Erythema/ No	1.0 cm/ Flat skin
505008/ 4477/IGlar/ 5[redacted]/Male/2[redacted]	1	Injection site erythema/ Abdominal local eritema at injection site/ 20JUL2021/100/20	Non-serious/ Mild/ Recovered/resolved	IGlar/ 20JUL2021/19 U	Yes: Burning/ Erythema/ No	3.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
715004/ 4477/IGlar/ 7[redacted]/Male/3[redacted]	3	Injection site erythema/ Localized skin reaction at injection site - redness/ 06APR2021/ 58/7	Non-serious/ Mild/ Recovered/resolved	IGlar/ 06APR2021/31 U	No/ Erythema/ No	2.5 cm/ Flat skin
801009/ 4477/IGlar/ 5[redacted]/Female/2[redacted]	1	Injection site pain/ Pain after insulin application at the injection site/ 13MAY2021/ 45/60	Non-serious/ Mild/ Recovered/resolved	IGlar/ 18MAY2021/28 U	Yes: Burning/ Erythema/ Unknown	1.0 cm/ Skin fold
204006/ 4478/Ico/ 7[redacted]/Female/1[redacted]	1	Soft tissue swelling/ Soft tissue swelling abdomen left side/ 01JUL2021/ 22/	Non-serious/ Mild/ Not recovered/not resolved	Ico/ 24JUN2021/60 U	No/ Induration/ No	2.0 in/ Flat skin
204006/ 4478/Ico/ 7[redacted]/Female/1[redacted]	2	Soft tissue swelling/ Soft tissue swelling abdomen right side/ 06JUL2021/ 27/	Non-serious/ Mild/ Not recovered/not resolved	Ico/ 01JUL2021/60 U	No/ Induration/ No	0.5 in/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
204006/ 4478/Ico/ 7[redacted]/Female/1[redacted]	7	Soft tissue swelling/ Soft tissue swelling left thigh/ 25OCT2021/138/	Non-serious/ Mild/ Not recovered/not resolved	Ico/ 21OCT2021/120 U	No/ Induration/ No	2.0 in/ Flat skin
208005/ 4478/Ico/ 6[redacted]/Male/3[redacted]	1	Injection site reaction/ Injection site reaction(abdomen)/ 21MAY2021/ 15/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 21MAY2021/300 U	Yes: Pain/ Erythema/ No	3.5 cm/ Flat skin
227005/ 4478/Ico/ 5[redacted]/Male/2[redacted]	1	Injection site swelling/ Swelling at injection site after each icodec injection/ 19MAY2021/ 8/9	Non-serious/ Mild/ Recovered/resolved	Ico/ 19MAY2021/530 U	Yes: Pain/ Induration; Other: Other/ No	0.7 in/ Flat skin
402005/ 4478/Ico/ 6[redacted]/Female/3[redacted]	2	Injection site reaction/ Injection site reaction (redness,itching)/ 19MAY2021/ 16/16	Non-serious/ Mild/ Recovered/resolved	Ico/ 18MAY2021/130 U	Yes: Itching/ Erythema/ No	3.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
208004/ 4478/IDeg/ 6[redacted]/Female/3[redacted]	1	Injection site reaction/ Injection site reaction(abdomen)/ 17JUN2021/ 56/4	Non-serious/ Mild/ Recovered/resolved	IDeg/ 17JUN2021/47 U	Yes: Pain/ Ecchymosis; Induration/ Other: Injected at slight angle	2.0 cm/ Flat skin
106008/ 4479/Ico/ 3[redacted]/Female/2[redacted]	1	Injection site pain/ Pain at injection site/ 11AUG2021/ 43/144	Non-serious/ Mild/ Recovered/resolved	Placebo/ 11AUG2021/27 U	Yes: Pain/ Cavities/ Unknown	0.5 cm/ Flat skin
107007/ 4479/Ico/ 3[redacted]/Female/2[redacted]	5	Injection site reaction/ Injection site reaction/ 03JAN2022/157/39	Non-serious/ Mild/ Recovered/resolved	Placebo/ 03JAN2022/39 U	No/ Induration/ No	0.8 cm/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	2	Injection site pruritus/ Pruritus at injection site/ 25AUG2021/ 87/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 24AUG2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	3	Injection site pruritus/ Pruritus at injection site/ 01SEP2021/ 94/2	Non-serious/ Mild/ Recovered/resolved	Ico/ 31AUG2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	4	Injection site pruritus/ Pruritus at injection site/ 08SEP2021/101/2	Non-serious/ Mild/ Recovered/resolved	Ico/ 07SEP2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	5	Injection site pruritus/ Pruritus at injection site/ 15SEP2021/108/2	Non-serious/ Mild/ Recovered/resolved	Ico/ 14SEP2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	6	Injection site pruritus/ Pruritus at injection site/ 22SEP2021/115/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 21SEP2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	7	Injection site pruritus/ Pruritus at injection site/ 29SEP2021/122/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 28SEP2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	8	Injection site pruritus/ Pruritus at injection site/ 09OCT2021/132/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 08OCT2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	9	Injection site pruritus/ Pruritus at injection site/ 15OCT2021/138/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 14OCT2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	10	Injection site pruritus/ Pruritus at injection site/ 22OCT2021/145/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 21OCT2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	11	Injection site pruritus/ Pruritus at injection site/ 29OCT2021/152/5	Non-serious/ Mild/ Recovered/resolved	Ico/ 28OCT2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	12	Injection site pruritus/ Pruritus at injection site/ 03NOV2021/157/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 02NOV2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	13	Injection site pruritus/ Pruritus at injection site/ 10NOV2021/164/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 09NOV2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	14	Injection site pruritus/ Pruritus at injection site/ 17NOV2021/171/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 16NOV2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
108002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	15	Injection site pruritus/ Pruritus at injection site/ 24NOV2021/178/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 23NOV2021/110 U	Yes: Itching/ Induration; Erythema/ No	/ Flat skin
113001/ 4479/Ico/ 3[redacted]/Female/2[redacted]	1	Injection site haemorrhage/ Ecchymosis at the injection site/ 01JUN2021/ 13/8	Non-serious/ Mild/ Recovered/resolved	Placebo/ 01JUN2021/13 U	No/ Cavities; Ecchymosis/ No	1.5 cm/ Flat skin
113002/ 4479/Ico/ 5[redacted]/Female/2[redacted]	1	Injection site pruritus/ Pruritus at injection site/ 06OCT2021/ 71/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 06OCT2021/210 U	Yes: Itching/ Cavities/ No	2.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
113002/ 4479/Ico/ 5[redacted]/Female/2[redacted]	2	Injection site pruritus/ Pruritus at injection site/ 18NOV2021/114/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 18NOV2021/230 U	Yes: Itching/ Other: There are no objective reactions related to injection site reactions./ No	3.0 cm/ Flat skin
113002/ 4479/Ico/ 5[redacted]/Female/2[redacted]	3	Injection site pruritus/ Pruritus at injection site/ 24NOV2021/120/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 24NOV2021/230 U	Yes: Itching/ Other: Na/ No	2.0 cm/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	3	Injection site reaction/ Injection site reaction (burning/ bruising)/ 21OCT2021/ 1/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 21OCT2021/70 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	4	Injection site reaction/ Injection site reaction (bruising/ burning)/ 28OCT2021/ 8/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 28OCT2021/90 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	10	Injection site reaction/ Injection site reaction (bruising/ burning)/ 04NOV2021/ 15/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 04NOV2021/110 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	11	Injection site reaction/ Injection site reaction (bruising/ burning)/ 11NOV2021/ 22/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 11NOV2021/130 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	12	Injection site reaction/ Injection site reaction (bruising/ burning)/ 18NOV2021/ 29/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 18NOV2021/150 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	14	Injection site reaction/ Injection site reaction (bruising/ burning)/ 03DEC2021/ 44/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 03DEC2021/170 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	15	Injection site reaction/ Injection site reaction (bruising/ burning)/ 09DEC2021/ 50/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 09DEC2021/190 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	16	Injection site reaction/ Injection site reaction (bruising/ burning)/ 17DEC2021/ 58/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 17DEC2021/190 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	17	Injection site reaction/ Injection site reaction (bruising/ burning)/ 23DEC2021/ 64/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 23DEC2021/190 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin
304003/ 4479/Ico/ 5[redacted]/Male/2[redacted]	18	Injection site reaction/ Injection site reaction (bruising/ burning)/ 30DEC2021/ 71/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 30DEC2021/190 U	Yes: Burning/ Ecchymosis/ No	1.0 in/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
315017/ 4479/Ico/ 7[redacted]/Female/3[redacted]	2	Injection site reaction/ Injection site reaction/ 21JAN2022/ 89/25	Non-serious/ Mild/ Recovered/resolved	Placebo/ 21JAN2022/36 U	Yes: Pain/ Ecchymosis; Erythema/ No	1.5 in/ Flat skin
315017/ 4479/Ico/ 7[redacted]/Female/3[redacted]	3	Injection site reaction/ Injection site reaction/ 28JAN2022/ 96/18	Non-serious/ Mild/ Recovered/resolved	Ico/ 28JAN2022/290 U	Yes: Burning/ Induration; Erythema/ No	4.0 in/ Flat skin
315017/ 4479/Ico/ 7[redacted]/Female/3[redacted]	4	Injection site reaction/ Injection site reaction/ 21MAR2022/148/15	Non-serious/ Mild/ Recovered/resolved	Ico/ 21MAR2022/390 U	Yes: Itching; Pain/ Induration; Erythema/ No	4.0 cm/ Flat skin
315017/ 4479/Ico/ 7[redacted]/Female/3[redacted]	5	Injection site reaction/ Injection site reaction/ 11APR2022/169/18	Non-serious/ Mild/ Recovered/resolved	Ico/ 11APR2022/390 U	Yes: Itching; Burning/ Erythema/ No	2.5 in/ Flat skin
315017/ 4479/Ico/ 7[redacted]/Female/3[redacted]	6	Injection site reaction/ Injection site reaction (left leg)/ 18APR2022/176/11	Non-serious/ Mild/ Recovered/resolved	Ico/ 18MAR2022/390 U	Yes: Itching; Burning; Pain/ Erythema/ No	3.0 in/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
320001/ 4479/Ico/ 4[redacted]/Male/2[redacted]	1	Injection site erythema/ Right thigh injection site redness/ 01MAY2021/ 13/6	Non-serious/ Mild/ Recovered/resolved	Placebo/ 01MAY2021/16 U	No/ Erythema/ No	1.5 cm/ Skin fold
330002/ 4479/Ico/ 5[redacted]/Male/3[redacted]	2	Injection site pain/ Right leg pain at injection site/ 15DEC2021/ 92/64	Non-serious/ Moderate/ Recovered/resolved	Placebo/ 15DEC2021/36 U	Yes: Pain/ Other: Bruising/ No	1.0 in/ Skin fold
508002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	4	Injection site reaction/ Injection site reaction/ 08OCT2021/ 23/6	Non-serious/ Mild/ Recovered/resolved	Ico/ 08OCT2021/110 U	Yes: Itching; Other: Redness/ Other: Swelling/ No	2.5 cm/ Flat skin
508002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	5	Injection site reaction/ Reaction site injection/ 14OCT2021/ 29/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 14OCT2021/110 U	Yes: Itching/ Erythema; Other: Pruritis/ No	1.5 cm/ Flat skin
508002/ 4479/Ico/ 6[redacted]/Female/2[redacted]	7	Injection site pain/ Injection site pain/ 15NOV2021/ 61/137	Non-serious/ Moderate/ Recovered/resolved	Ico/ 11NOV2021/70 U	Yes: Pain/ Erythema; Other: Redness/ No	1.5 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
704001/ 4479/Ico/ 7[redacted]/Female/2[redacted]	1	Injection site erythema/ Red spot right thigh injection site/ 20MAY2021/ 10/48	Non-serious/ Mild/ Recovered/resolved	Placebo/ 20MAY2021/13 U	Yes: Other: Redness/ Other: Redness/ No	0.3 cm/ Flat skin
704001/ 4479/Ico/ 7[redacted]/Female/2[redacted]	2	Injection site erythema/ Little red spot with white dot in the middle on right thigh injection site/ 23JUL2021/ 74/40	Non-serious/ Mild/ Recovered/resolved	Placebo/ 23JUL2021/33 U	Yes: Other: Redness/ Other: White dot in the middle of redness/ No	0.5 cm/ Skin fold
704001/ 4479/Ico/ 7[redacted]/Female/2[redacted]	3	Injection site erythema/ Little red spot with scab on right thigh injection site/ 20JUL2021/ 71/43	Non-serious/ Mild/ Recovered/resolved	Placebo/ 20JUL2021/33 U	Yes: Other: Redness/ Other: Scab/ No	0.5 cm/ Skin fold
704003/ 4479/Ico/ 6[redacted]/Male/2[redacted]	3	Injection site haemorrhage/ Right thigh side injection ecchymosis/ 22OCT2021/163/16	Non-serious/ Mild/ Recovered/resolved	Placebo/ 22OCT2021/30 U	No/ Ecchymosis/ No	1.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
712008/ 4479/Ico/ 4[redacted]/Male/2[redacted]	1	Injection site swelling/ Injection site reaction swelling (single ae)/ 22OCT2021/107/42	Non-serious/ Mild/ Recovered/resolved	Ico/ 15OCT2021/350 U	Yes: Itching; Other: Swelling at injection site (left thigh)/ Other: Swelling at injection site (no redness or pain)/ No	8.0 cm/ Flat skin
716005/ 4479/Ico/ 5[redacted]/Male/3[redacted]	2	Injection site reaction/ Injection site reaction/ 03DEC2021/ 25/5	Non-serious/ Mild/ Recovered/resolved	Ico/ 30NOV2021/130 U	Yes: Itching; Other: Warm/ Erythema/ No	4.0 cm/ Skin fold
802009/ 4479/Ico/ 5[redacted]/Male/2[redacted]	1	Injection site reaction/ Injection site reaction/ 28OCT2021/ 45/8	Non-serious/ Mild/ Recovered/resolved	Placebo/ 28OCT2021/19 U	No/ Other: Swelling/ No	1.0 cm/ Flat skin
802010/ 4479/Ico/ 4[redacted]/Female/3[redacted]	1	Injection site reaction/ Injection site reaction/ 24NOV2021/ 63/17	Non-serious/ Mild/ Recovered/resolved	Ico/ 24NOV2021/250 U	Yes: Pain/ Other: Swelling/ No	1.5 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
902003/ 4479/Ico/ 6[redacted]/Male/2[redacted]	2	Injection site haematoma/ Haematoma, right thigh, at site of injection/ 05JUL2021/ 33/9	Non-serious/ Mild/ Recovered/resolved	Placebo/ 05JUL2021/16 U	No/ Haematoma/ Other: Anticoagulant treatment	1.0 cm/ Flat skin
902003/ 4479/Ico/ 6[redacted]/Male/2[redacted]	3	Injection site haematoma/ Haematoma at injection site on right thigh/ 06JUL2021/ 34/8	Non-serious/ Mild/ Recovered/resolved	Placebo/ 06JUL2021/16 U	No/ Haematoma/ Other: Anticoagulant treatment	1.0 cm/ Flat skin
902003/ 4479/Ico/ 6[redacted]/Male/2[redacted]	9	Injection site haematoma/ Haematoma 1 cm right thigh, injection site/ 27SEP2021/117/11	Non-serious/ Mild/ Recovering/resolving	Placebo/ 27SEP2021/21 U	No/ Haematoma/ No	1.0 cm/ Flat skin
902003/ 4479/Ico/ 6[redacted]/Male/2[redacted]	10	Injection site haematoma/ Haematoma 2 cm right thigh, injection site/ 01OCT2021/121/7	Non-serious/ Mild/ Recovering/resolving	Placebo/ 01OCT2021/21 U	No/ Haematoma/ No	2.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
902004/ 4479/Ico/ 7[redacted]/Male/2[redacted]	2	Injection site haematoma/ Hematoma, right thigh, at injection site/ 26JUN2021/ 17/10	Non-serious/ Mild/ Recovered/resolved	Placebo/ 26JUN2021/16 U	Yes: Other: Very small drop of blood/ Haematoma/ Other: Slim thighs	0.5 cm/ Flat skin
902004/ 4479/Ico/ 7[redacted]/Male/2[redacted]	3	Injection site haematoma/ Haematoma, right thigh 3 cm, injection site/ 08OCT2021/121/7	Non-serious/ Mild/ Recovering/resolving	Placebo/ 08OCT2021/27 U	No/ Haematoma/ Family history of allergies or intolerances: Pen slipped in subjects hand during injection	3.0 cm/ Flat skin
951011/ 4479/Ico/ 5[redacted]/Female/2[redacted]	10	Application site pruritus/ Reaction to medication (application site itching)/ 02MAR2022/176/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 02MAR2022/190 U	Yes: Itching/ / No	/ Flat skin
954002/ 4479/Ico/ 5[redacted]/Female/3[redacted]	1	Application site bruise/ Bruise at the application site/ 02AUG2021/ 2/16	Non-serious/ Mild/ Recovered/resolved	Ico/ 01AUG2021/70 U	No/ Ecchymosis/ No	3.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
954003/ 4479/Ico/ 5[redacted]/Male/3[redacted]	2	Injection site reaction/ Reaction to injection/ 06DEC2021/100/80	Non-serious/ Mild/ Recovered/resolved	Placebo/ 06DEC2021/50 U	Yes: Burning; Pain/ / No	/ Flat skin
954014/ 4479/Ico/ 3[redacted]/Male/3[redacted]	3	Injection site reaction/ Local reaction to injection/ 25JAN2022/112/15	Non-serious/ Mild/ Recovering/resolving	Ico/ 19JAN2022/330 U	No/ Oedema/ No	/ Flat skin
105009/ 4479/IDeg/ 5[redacted]/Male/2[redacted]	1	Injection site pruritus/ Itching at injection site in right thigh/ 05JAN2022/111/43	Non-serious/ Mild/ Recovered/resolved	IDeg/ 05JAN2022/24 U	Yes: Itching/ Other: No objective signs/ No	3.0 cm/ Flat skin
106025/ 4479/IDeg/ 5[redacted]/Female/2[redacted]	1	Injection site induration/ Induration of injection site in right thigh/ 07JAN2022/106/82	Non-serious/ Mild/ Recovered/resolved	IDeg/ 07JAN2022/16 U	Yes: Other: Acid distension of right anterolateral thigh/ Induration/ No	1.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
112003/ 4479/IDeg/ 3[redacted]/Male/2[redacted]	2	Injection site pain/ Pain at injection site of right leg/ 18NOV2021/ 41/45	Non-serious/ Mild/ Recovered/resolved	IDeg/ 18NOV2021/16 U	Yes: Pain/ Other: Na/ No	/ Flat skin
312006/ 4479/IDeg/ 7[redacted]/Male/3[redacted]	1	Injection site reaction/ Injection site reaction/ 21NOV2021/ 13/1	Non-serious/ Mild/ Recovered/resolved	IDeg/ 21NOV2021/10 U	Yes: Pain/ Haemorrhage; Oedema/ No	0.0 cm/ Flat skin
319003/ 4479/IDeg/ 7[redacted]/Female/2[redacted]	3	Injection site reaction/ Bump at injection site/ 28OCT2021/158/1	Non-serious/ Mild/ Recovered/resolved	IDeg/ 28OCT2021/19 U	No/ Other: Bump at injection site/ No	0.2 cm/ Flat skin
704002/ 4479/IDeg/ 6[redacted]/Female/2[redacted]	6	Injection site swelling/ Swelling in the right thigh injection site/ 15SEP2021/127/62	Non-serious/ Mild/ Recovered/resolved	IDeg/ 14SEP2021/16 U	Yes: Other: Swelling/ Oedema/ No	8.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
704002/ 4479/IDeg/ 6[redacted]/Female/2[redacted]	9	Injection site haemorrhage/ Ecchymosis in the right thigh injection site/ 27SEP2021/139/26	Non-serious/ Mild/ Recovered/resolved	IDeg/ 26SEP2021/70 U	Yes: Other: Ecchymosis/ Ecchymosis/ No	1.0 cm/ Skin fold
704002/ 4479/IDeg/ 6[redacted]/Female/2[redacted]	10	Injection site pain/ Burning sensation in the right thigh injection site/ 22SEP2021/134/1	Non-serious/ Mild/ Recovered/resolved	IDeg/ 21SEP2021/16 U	Yes: Burning/ Other: Burning sensation/ No	/ Skin fold
704004/ 4479/IDeg/ 6[redacted]/Female/3[redacted]	1	Injection site pain/ Pain at thighs injection sites/ 19AUG2021/ 43/48	Non-serious/ Mild/ Recovered/resolved	Placebo/ 12AUG2021/10 U	Yes: Pain/ / No	/ Skin fold
	1	Injection site pain/ Pain at thighs injection sites/ 19AUG2021/ 43/48	Non-serious/ Mild/ Recovered/resolved	IDeg/ 18AUG2021/10 U	Yes: Pain/ / No	/ Skin fold
704010/ 4479/IDeg/ 6[redacted]/Male/2[redacted]	5	Injection site oedema/ Daily injection site edema on right thigh/ 07APR2022/178/15	Non-serious/ Mild/ Recovered/resolved	IDeg/ 07APR2022/19 U	Yes: Other: Swelling/ Oedema/ No	4.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
713005/ 4479/IDeg/ 5[redacted]/Male/2[redacted]	1	Injection site bruising/ Intermittent site injection reaction (bruises on right tight)/ 01NOV2021/ 29/43	Non-serious/ Mild/ Recovered/resolved	IDeg/ 01NOV2021/22 U	Yes: Other: Bruises/ Ecchymosis/ No	1.0 cm/ Flat skin
902002/ 4479/IDeg/ 4[redacted]/Female/3[redacted]	2	Injection site haematoma/ Haematoma right thigh (injection site)/ 05JUL2021/ 35/12	Non-serious/ Mild/ Recovered/resolved	IDeg/ 05JUL2021/21 U	No/ Haematoma/ No	2.5 cm/ Skin fold
902005/ 4479/IDeg/ 6[redacted]/Female/1[redacted]	1	Injection site haematoma/ Haematoma 2x2 cm, right thigh in area of injection/ 21JUN2021/ 7/7	Non-serious/ Mild/ Recovered/resolved	IDeg/ 21JUN2021/10 U	Yes: Pain; Other: Drop of blood after injection/ Haematoma/ No	2.0 cm/ Flat skin
902005/ 4479/IDeg/ 6[redacted]/Female/1[redacted]	2	Injection site haematoma/ Haematoma at injection site on right thigh/ 28JUN2021/ 14/6	Non-serious/ Mild/ Recovered/resolved	IDeg/ 28JUN2021/10 U	Yes: Other: Blod drop/ Haematoma/ No	1.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
902005/ 4479/IDeg/ 6[redacted]/Female/1[redacted]	3	Injection site haematoma/ Haematoma, right thigh in area of injection/ 05JUL2021/ 21/7	Non-serious/ Mild/ Recovered/resolved	IDeg/ 05JUL2021/10 U	No/ Haematoma/ No	1.0 cm/ Skin fold
902005/ 4479/IDeg/ 6[redacted]/Female/1[redacted]	4	Injection site haematoma/ Haematoma, right thigh in area of injection/ 16JUL2021/ 32/7	Non-serious/ Mild/ Recovered/resolved	IDeg/ 16JUL2021/10 U	No/ Haematoma/ No	1.5 cm/ Flat skin
902005/ 4479/IDeg/ 6[redacted]/Female/1[redacted]	5	Injection site haematoma/ Haematoma, right thigh 1*1 cm in area of injection/ 18AUG2021/ 65/6	Non-serious/ Mild/ Recovered/resolved	IDeg/ 18AUG2021/10 U	No/ Haematoma/ No	1.1 cm/ Flat skin
902005/ 4479/IDeg/ 6[redacted]/Female/1[redacted]	6	Injection site pain/ Soreness, right thigh in the area of injections/ 24JUL2021/ 40/11	Non-serious/ Mild/ Recovered/resolved	IDeg/ 24JUL2021/10 U	Yes: Pain; Other: Overall feeling of soreness in injection area/ Other: No specific signs/ Other: Low bodyweight and slim thighs	15.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
902006/ 4479/IDeg/ 5[redacted]/Female/1[redacted]	2	Injection site pain/ Pain, when needle penetrates the skin on left thigh./ 13OCT2021/ 57/1	Non-serious/ Mild/ Recovered/resolved	Placebo/ 13OCT2021/70 U	Yes: Pain/ Other: No objective signs/ No	0.0 cm/ Flat skin
902007/ 4479/IDeg/ 7[redacted]/Male/2[redacted]	1	Injection site haematoma/ Heamatoma at injection site on right thigh/ 01OCT2021/ 18/12	Non-serious/ Mild/ Recovered/resolved	IDeg/ 01OCT2021/13 U	No/ Haematoma/ No	1.5 cm/ Flat skin
902007/ 4479/IDeg/ 7[redacted]/Male/2[redacted]	2	Injection site haematoma/ Haematoma at injection site on right thigh/ 24OCT2021/ 41/10	Non-serious/ Mild/ Recovered/resolved	IDeg/ 24OCT2021/16 U	Yes: Other: Soreness/ Haematoma/ No	2.1 cm/ Flat skin
902007/ 4479/IDeg/ 7[redacted]/Male/2[redacted]	5	Injection site pain/ Soreness at injection site, right thigh/ 26FEB2022/166/53	Non-serious/ Mild/ Recovering/resolving	IDeg/ 26FEB2022/30 U	Yes: Other: Soreness/ Other: No/ No	10.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
420002/ 4480/Ico/ 6[redacted]/Female/3[redacted]	2	Injection site reaction/ Possible injection site reaction/ 16JUN2021/ 16/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 15JUN2021/180 U	No/ Erythema/ Other: Personal history of hives with cefzil and redness from neosporin	1.0 in/ Skin fold
516013/ 4480/Ico/ 5[redacted]/Male/2[redacted]	2	Injection site reaction/ Local injection site reaction/ 25OCT2021/ 60/4	Non-serious/ Mild/ Recovered/resolved	Ico/ 25OCT2021/310 U	No/ Other: Other/ No	1.0 in/ Skin fold
515011/ 4480/IGlar/ 2[redacted]/Male/2[redacted]	1	Injection site rash/ Injection site rash/ 04APR2022/175/6	Non-serious/ Mild/ Recovered/resolved	IGlar/ 03APR2022/30 U	No/ Other: Other/ No	3.0 cm/ Skin fold
601004/ 4480/IGlar/ 6[redacted]/Male/2[redacted]	1	Injection site pain/ Pain at the injection site for 1 minute./ 04AUG2021/ 1/41	Non-serious/ Mild/ Recovered/resolved	IGlar/ 04AUG2021/34 U	Yes: Pain/ Other: Other/ No	0.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
529002/ 4481/Ico/ 4[redacted]/Male/3[redacted]	5	Injection site pruritus/ Injection site reaction - itching/ 21OCT2021/141/	Non-serious/ Mild/ Not recovered/not resolved	Ico/ 21OCT2021/310 U	Yes: Itching/ Other: Itchy and tenderness/ No	/ Flat skin
801001/ 4481/Ico/ 6[redacted]/Female/2[redacted]	1	Injection site pruritus/ Itchiness on injection site - abdomen/ 05JUN2021/ 87/284	Non-serious/ Mild/ Recovered/resolved	Ico/ 03JUN2021/190 U	Yes: Itching/ Other: Unknown/ No	3.0 cm/ Flat skin
848004/ 4481/Ico/ 4[redacted]/Male/2[redacted]	2	Injection site mass/ Raised bumped at injection site/ 10DEC2021/176/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 10DEC2021/330 U	No/ Erythema/ No	/ Flat skin
541001/ 4481/OD analogues/ 6[redacted]/Female/4[redacted]	5	Injection site induration/ Induration at insulin degludec injection site, left abdomen/ 27JUL2021/ 78/97	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 26JUL2021/60 U	No/ Induration/ No	1.0 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	3	Injection site pain/ Injection site reaction tenderness (isr)/ 01JUL2021/ 24/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 01JUL2021/19 U	Yes: Pain/ Other: No local objective signs associated with injection site reaction/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	4	Injection site pain/ Injection site reaction tenderness (isr)/ 06JUL2021/ 29/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 06JUL2021/19 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	5	Injection site pain/ Injection site reaction tenderness (isr)/ 08JUL2021/ 31/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 08JUL2021/22 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	6	Injection site pain/ Injection site reaction tenderness (isr)/ 19JUL2021/ 42/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 19JUL2021/35 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	7	Injection site pain/ Injection site reaction tenderness (isr)/ 24JUL2021/ 47/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 24JUL2021/28 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	8	Injection site pain/ Injection site reaction tenderness (isr)/ 30JUL2021/ 53/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 30JUL2021/31 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	9	Injection site pain/ Injection site reaction tenderness (isr)/ 04AUG2021/ 58/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 04AUG2021/31 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	10	Injection site pain/ Injection site reaction tenderness (isr)/ 07AUG2021/ 61/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 07AUG2021/34 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
nn1436/nn1436-iss/submission_20221024_er
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	11	Injection site pain/ Injection site reaction tenderness (isr)/ 10AUG2021/ 64/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 10AUG2021/34 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	12	Injection site pain/ Injection site reaction tenderness (isr)/ 20AUG2021/ 74/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 20AUG2021/34 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	13	Injection site pain/ Injection site reaction tenderness (isr)/ 27AUG2021/ 81/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 27AUG2021/37 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	14	Injection site pain/ Injection site reaction tenderness (isr)/ 04SEP2021/ 89/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 04SEP2021/40 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	15	Injection site pain/ Injection site reaction tenderness (isr)/ 13SEP2021/ 98/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 13SEP2021/43 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	16	Injection site pain/ Injection site reaction tenderness (isr)/ 26SEP2021/111/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 26SEP2021/49 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	17	Injection site pain/ Injection site reaction tenderness (isr)/ 02OCT2021/117/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 02OCT2021/52 U	Yes: Pain/ Other: None/ No	0.0 / Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	18	Injection site pain/ Injection site reaction tenderness (isr)/ 06OCT2021/121/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 06OCT2021/55 U	Yes: Pain/ Other: None/ No	0.0 cm/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	19	Injection site pain/ Injection site reaction tenderness (isr)/ 28NOV2021/174/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 28NOV2021/67 U	Yes: Other: Tenderness/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	20	Injection site pain/ Injection site reaction tenderness (isr)/ 06DEC2021/182/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 06DEC2021/70 U	Yes: Other: Tenderness/ Other: None/ No	0.0 cm/ Skin fold
559004/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	21	Injection site pain/ Injection site reaction tenderness (isr)/ 13DEC2021/189/1	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 13DEC2021/73 U	Yes: Other: Tenderness/ Other: None/ No	0.0 cm/ Skin fold
589001/ 4481/OD analogues/ 6[redacted]/Female/4[redacted]	1	Injection site bruising/ Bruising at injection site on leg/ 10JUN2021/ 43/29	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 10JUN2021/22 U	No/ Ecchymosis/ No	1.0 in/ Skin fold

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
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Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
591002/ 4481/OD analogues/ 6[redacted]/Female/2[redacted]	4	Injection site pain/ Intermittent burning sensation around injection site/ 22JUN2021/ 1/	Non-serious/ Moderate/ Not recovered/not resolved	OD analogues/ 22JUN2021/10 U	Yes: Burning/ Other: None/ No	2.0 cm/ Flat skin
801018/ 4481/OD analogues/ 6[redacted]/Male/2[redacted]	1	Injection site reaction/ Injection site reaction - left quadrant/ 06AUG2021/ 39/137	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 06AUG2021/22 U	Yes: Itching/ Induration/ Unknown	3.7 cm/ Flat skin
801018/ 4481/OD analogues/ 6[redacted]/Male/2[redacted]	2	Injection site reaction/ Injection site reaction - right quadrant/ 03AUG2021/ 36/140	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 03AUG2021/21 U	Yes: Itching/ Induration/ Unknown	3.4 cm/ Flat skin
801018/ 4481/OD analogues/ 6[redacted]/Male/2[redacted]	3	Injection site reaction/ Injection site reaction - upper quadrant/ 13AUG2021/ 46/130	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 13AUG2021/23 U	Yes: Itching/ Induration/ Unknown	2.3 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
812008/ 4481/OD analogues/ 6[redacted]/Male/2[redacted]	1	Injection site reaction/ Site injection reaction (abdomen)/ 03AUG2021/ 77/189	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 03AUG2021/44 U	No/ Erythema/ No	3.0 cm/ Flat skin
835001/ 4481/OD analogues/ 6[redacted]/Male/2[redacted]	1	Injection site bruising/ Injection site reaction-local bruising on right side abdomen/ 04AUG2021/ 59/5	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 04AUG2021/6 U	Yes: Pain/ Other: Bruising/ No	0.3 cm/ Flat skin
835001/ 4481/OD analogues/ 6[redacted]/Male/2[redacted]	2	Injection site pain/ Pain at injection site/ 19JAN2022/227/21	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 19JAN2022/7 U	Yes: Pain/ Other: No local objective sign/ No	2.0 cm/ Flat skin
609001/ 4625/Ico/ 3[redacted]/Female/2[redacted]	1	Injection site urticaria/ Red colored wheal at the injection site (asymptomatic)/ 01SEP2021/ 8/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 01SEP2021/80 U	No/ Induration; Erythema/ Other: Lantus allergy many years ago	0.3 in/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"

Injection site reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Symptoms/ Objective signs/ Risk or confounding factors	Max size/ Skin fold or flat skin
609001/ 4625/Ico/ 3[redacted]/Female/2[redacted]	3	Injection site urticaria/ Clear wheal following a single injection of insulin on 9/26/2021 at the site of the insulin injection/ 26SEP2021/ 33/1	Non-serious/ Mild/ Recovered/resolved	/ /	No/ Induration/ Other: Previous site of injection reaction	/
302005/ 4625/IDeg/ 4[redacted]/Male/2[redacted]	7	Injection site pain/ Burning sensation after injecting degludec on upper buttocks/ 24DEC2021/100/57	Non-serious/ Mild/ Recovered/resolved	IDeg/ 24DEC2021/7 U	Yes: Itching; Burning/ Other: Other/ No	3.0 cm/ Flat skin
306008/ 4625/IDeg/ 5[redacted]/Female/3[redacted]	3	Injection site mass/ Red, itchy lumps following injection of degludec./ 17NOV2021/ 51/14	Non-serious/ Mild/ Recovered/resolved	IDeg/ 17NOV2021/74 U	Yes: Itching/ Induration; Erythema/ No	0.8 cm/ Flat skin
	3	Injection site mass/ Red, itchy lumps following injection of degludec./ 17NOV2021/ 51/14	Non-serious/ Mild/ Recovered/resolved	IDeg/ 18NOV2021/6 U	Yes: Itching/ Induration; Erythema/ No	0.8 cm/ Flat skin
	3	Injection site mass/ Red, itchy lumps following injection of degludec./ 17NOV2021/ 51/14	Non-serious/ Mild/ Recovered/resolved	IDeg/ 18NOV2021/68 U	Yes: Itching/ Induration; Erythema/ No	0.8 cm/ Flat skin

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES FAORRESU; criteria: FAOBJ == "INJECTION SITE REACTION"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
suppze.xpt; variable(s): QVAL; criteria: QNAM == "ISRMETHD"
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7.3.138 Systemic hypersensitivity reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Signs or symptoms present during event/ Risk or confounding factors	Immunological test/ Previous reaction to trial product
124004/ 4477/IGlar/ 6[redacted]/Female/3[redacted]	6	Urticaria/ Hives/ 13SEP2021/193/176	Non-serious/ Moderate/ Recovered/resolved	IGlar/ 13SEP2021/25 U	Yes: Generalised urticaria/ Unknown	No/ No
154001/ 4477/Ico/ 5[redacted]/Female/2[redacted]	11	Angioedema/ Allergic reaction with facial angioedema due to changing from trade vascepa to generic vascepa/ 21OCT2021/311/5	Non-serious/ Mild/ Recovered/resolved	Ico/ 19OCT2021/550 U	Yes: Angiooedema/ No	No/ No
204016/ 4477/IGlar/ 6[redacted]/Male/2[redacted]	3	Angioedema/ Angioedema associated with food allergies/ 06APR2022/346/1	Non-serious/ Moderate/ Recovered/resolved	IGlar/ 05APR2022/13 U	Yes: Angiooedema/ Other: The patient had eaten seafood the night before.	No/ No
505005/ 4477/IGlar/ 7[redacted]/Female/2[redacted]	1	Urticaria/ Urticaria in both hands due to paracetamol/ 27MAY2021/ 65/2	Non-serious/ Mild/ Recovered/resolved	IGlar/ 27MAY2021/25 U	Yes: Other/ Other: Pacient had similar episodes before de study with paracetamol	No/ No

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1SYM ACAT1RSK; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "HYPERSENSITIVITY"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Systemic hypersensitivity reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Signs or symptoms present during event/ Risk or confounding factors	Immunological test/ Previous reaction to trial product
701004/ 4477/Ico/ 6[redacted]/Male/3[redacted]	2	Pruritus/ Itchiness of skin all over body/ 05MAY2021/ 44/1	Non-serious/ Mild/ Recovered/resolved	Ico/ 04MAY2021/190 U	Yes: Generalised prickle sensation/ No	Yes/ No
851012/ 4477/Ico/ 6[redacted]/Male/3[redacted]	2	Drug intolerance/ Intolerance of metformin (diarrhoea)/ 15SEP2021/163/31	Non-serious/ Moderate/ Recovered/resolved	Ico/ 07SEP2021/490 U	Yes: Diarrhoea/ No	No/ No
205004/ 4478/Ico/ 7[redacted]/Male/2[redacted]	1	Urticaria/ Hives/ 17OCT2021/161/2	Non-serious/ Mild/ Recovered/resolved	Ico/ 11OCT2021/250 U	Yes: Generalised urticaria; generalised pruritus with skin rash/ No	No/ No
207003/ 4478/Ico/ 5[redacted]/Male/2[redacted]	1	Anaphylactic reaction/ Anaphylactic reaction to tylenol 3/ 02NOV2021/221/3	Serious/ Moderate/ Recovered/resolved	Ico/ 24SEP2021/290 U	Yes: Upper airway swelling/ Other: Allergic reaction to tylenol 3	No/ No

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1SYM ACAT1RSK; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "HYPERSENSITIVITY"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Systemic hypersensitivity reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Signs or symptoms present during event/ Risk or confounding factors	Immunological test/ Previous reaction to trial product
401002/ 4478/IDeg/ 7[redacted]/Female/2[redacted]	1	Anaphylactic reaction/ Anaphylactic reaction/ 15APR2021/ 2/1	Serious/ Severe/ Recovered/resolved	IDeg/ 14APR2021/10 U	Yes: Generalised erythema; generalised urticaria; generalised pruritus with skin rash; difficulty breathing without wheeze or stridor; sensation of throat closure; upper airway swelling; other/ No	No/ No
702003/ 4478/Ico/ 5[redacted]/Male/2[redacted]	2	Medical device site dermatitis/ Skin lesions scattered over the upper, lower limbs, trunk, back, abdomen and face. Probable contact dermatitis with the clinical trial sensor/ 30NOV2021/190/1	Non-serious/ Moderate/ Recovering/resolving	Ico/ 16NOV2021/210 U	Yes: Generalised erythema; generalised urticaria/ No	No/ No
903007/ 4478/Ico/ 5[redacted]/Male/2[redacted]	1	Urticaria/ Urticaria, whole body/ 18AUG2021/ 37/	Non-serious/ Severe/ Not recovered/not resolved	Ico/ 24AUG2021/410 U	Yes: Generalised urticaria/ No	Yes/ No

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1SYM ACAT1RSK; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "HYPERSENSITIVITY"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"

Systemic hypersensitivity reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Signs or symptoms present during event/ Risk or confounding factors	Immunological test/ Previous reaction to trial product
402018/ 4479/IDeg/ 6[redacted]/Female/2[redacted]	2	Urticaria/ Generalizared urticaria/ 01DEC2021/ 92/24	Non-serious/ Mild/ Recovered/resolved	Placebo/ 01DEC2021/290 U	Yes: Generalised urticaria/ No	No/ No
106005/ 4480/Ico/ 7[redacted]/Female/2[redacted]	1	Urticaria/ Urticaria/ 19JUN2021/ 5/82	Non-serious/ Moderate/ Recovered/resolved	Ico/ 15JUN2021/230 U	Yes: Generalised urticaria/ Other: Allergy to metals	Yes/ No
113006/ 4481/OD analogues/ 4[redacted]/Female/2[redacted]	1	Angioedema/ Angioedema (face)/ 13SEP2021/ 85/178	Non-serious/ Moderate/ Recovering/resolving	OD analogues/ 12SEP2021/16 U	Yes: Face,throat/ No	No/ No
113006/ 4481/OD analogues/ 4[redacted]/Female/2[redacted]	2	Urticaria/ Urticaria (face, throat)/ 30JUL2021/ 40/45	Non-serious/ Mild/ Recovered/resolved	OD analogues/ 29JUL2021/10 U	Yes: Urticaria (face and neck)/ No	No/ No
206003/ 4481/Ico/ 5[redacted]/Male/2[redacted]	2	Urticaria/ Urticaria/ 29JUN2021/ 22/17	Serious/ Severe/ Recovered/resolved	Ico/ 29JUN2021/70 U	Yes: Generalised urticaria/ No	No/ No

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "HYPERSENSITIVITY"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Systemic hypersensitivity reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Signs or symptoms present during event/ Risk or confounding factors	Immunological test/ Previous reaction to trial product
206003/ 4481/Ico/ 5[redacted]/Male/2[redacted]	4	Lip swelling/ Swelling in the lower lip/ 01JUL2021/ 24/2	Non-serious/ Mild/ Recovered/resolved	Ico/ 29JUN2021/70 U	Yes: Upper airway swelling/ No	No/ No
206003/ 4481/Ico/ 5[redacted]/Male/2[redacted]	5	Swelling face/ Swelling of face/ 02JUL2021/ 25/2	Non-serious/ Mild/ Recovered/resolved	Ico/ 29JUN2021/70 U	Yes: Swelling of face/ No	No/ No
535003/ 4481/Ico/ 6[redacted]/Male/2[redacted]	1	Paraesthesia/ Intermittent abnormal skin sensation/ 03MAY2021/ 8/3	Non-serious/ Moderate/ Recovered/resolved	Ico/ 03MAY2021/90 U	Yes: Generalised prickle sensation/ No	No/ No
535003/ 4481/Ico/ 6[redacted]/Male/2[redacted]	2	Paraesthesia/ Prickle sensation/ 15MAY2021/ 20/3	Non-serious/ Mild/ Recovered/resolved	Ico/ 03MAY2021/90 U	Yes: Generalised prickle sensation/ Unknown	No/ Unknown
547003/ 4481/OD analogues/ 5[redacted]/Female/2[redacted]	1	Pruritus/ Generalized itching, mainly over the back./ 19MAY2021/ 8/77	Non-serious/ Severe/ Recovered/resolved	OD analogues/ 18MAY2021/10 U	Yes: Generalised pruritus with skin rash/ No	No/ No

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "HYPERSENSITIVITY"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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Systemic hypersensitivity reactions - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Date/Day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved/ Date/Dose	Signs or symptoms present during event/ Risk or confounding factors	Immunological test/ Previous reaction to trial product
802002/ 4481/Ico/ 5[redacted]/Male/3[redacted]	1	Diarrhoea/ Diarrhea episode after each injection dose/ 28MAY2021/ 9/206	Non-serious/ Mild/ Recovered/resolved	Ico/ 27MAY2021/70 U	Yes: Diarrhoea/ No	Yes/ No
612004/ 4625/Ico/ 3[redacted]/Female/2[redacted]	1	Hypersensitivity/ Systemic allergic reaction without anaphylaxis. Symptoms included swelling of eyes/lips/neck as well as itching and hives covering torso./ 10SEP2021/ 95/7	Non-serious/ Severe/ Recovered/resolved	Ico/ 07SEP2021/180 U	Yes: Itchy eyes with or without chemosis; generalised urticaria; other/ Other: Eating at a new mexican restaurant as well as a new bakery the night before. Consumed a red velvet cake donut, which she has not had in many years.	Yes/ No
903013/ 4625/IDeg/ 2[redacted]/Female/2[redacted]	3	Rhinitis allergic/ Rhinitis allergic/ 05NOV2021/154/	Non-serious/ Mild/ Not recovered/not resolved	IDeg/ 05NOV2021/20 U	Yes: Sneezing; rhinorrhoea/ Other: Cat	Yes/ No

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "HYPERSENSITIVITY"
ze.xpt; variable(s): ZETRT ZEDOSE ZEDOSU ZESTDTC; criteria: ZESCAT == "DOSE AS REPORTED AS PART OF INJECT REAC"
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7.3.139 Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
133005/ 4477/Ico/ 6[redacted]/Male/2[redacted]	1	Overdose/ Overdose study medication error/ 95/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong frequency of administration: Higher frequency: Pt took 2 weekly doses in 1 week/ Other: patient thought it was tuesday the day he usually doses and it actually was thursday	Hypo no. : NA AE no. : NA
142002/ 4477/IGlar/ 7[redacted]/Female/2[redacted]	5	Overdose/ Overdosing of insulin/ 155/8	Non-serious/ Mild/ Recovered/ resolved	IGlar	Wrong dose administered: Overdose: Subject administered 80 IU instead of 77 IU/ Misunderstanding of training/verbal instruction	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
142002/ 4477/IGlar/ 7[redacted]/Female/2[redacted]	6	Underdose/ Underdosing of insulin/ 163/7	Non-serious/ Mild/ Recovered/ resolved	IGlar	Wrong dose administered: Underdose: Subject dosed 78 IU instead of the 80 IU prescribed by the PI on 23Jun2021/ Misunderstanding of training/verbal instruction	Hypo no. : NA AE no. : NA
210002/ 4478/Ico/ 7[redacted]/Male/2[redacted]	1	Accidental overdose/ Accidental overdose/ 8/1	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: PI prescribed the incorrect dose/ Miscalculation	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
210004/ 4478/Ico/ 6[redacted]/Female/2[redacted]	1	Accidental overdose/ Accidental overdose/ 2/1	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong frequency of administration: Higher frequency: subject dosed on 4-27-21 with icodec then again on 4-28-21 in error/ Other: patient was going about her usual nightly routine dosing with insulin, forgetting she was on a weekly dose. Patient immediately knew her mistake and called the site the next morning.	Hypo no. : 1, 2 AE no. : NA
220002/ 4478/Ico/ 7[redacted]/Female/2[redacted]	2	Accidental overdose/ Medication error [accidental administration of higher dose than intended]/ 9/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: did not calculate weekly dose correctly/ Miscalculation	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
302001/ 4478/Ico/ 6[redacted]/Female/3[redacted]	29	Overdose/ Dosing error / over dose/ 8/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: Patient Took 400u in error instead of 260u/ Misunderstanding of instructions for use	Hypo no. : 4, 5, 6, 7 AE no. : NA
302003/ 4478/Ico/ 7[redacted]/Male/2[redacted]	1	Overdose/ Dosing error over dose/ 8/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: Patient took the wrong dose 110u instead of 70u/ Misunderstanding of instructions for use	Hypo no. : NA AE no. : NA
302006/ 4478/Ico/ 5[redacted]/Female/3[redacted]	10	Underdose/ Medical dosing error, under dosing/ 1/8	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Underdose: Instead of 24u the patient was given 12u/ Miscalculation	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
303016/ 4478/Ico/ 6[redacted]/Male/2[redacted]	1	Accidental overdose/ Accidental overdose of imp/ 1/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: The Icodec dose was calculated accidently by using 52 units of basal insulin instead of 42 units/ Miscalculation	Hypo no. : NA AE no. : NA
211002/ 4478/IDeg/ 6[redacted]/Male/3[redacted]	3	Intentional overdose/ Intentional single overdose/ 4/1	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Overdose: Overuse of 10 units of study drug to bring down blood glucose level, patient did this once./ Other: overuse of 10 units of study drug to bring down blood glucose level, patient did this once.	Hypo no. : NA AE no. : NA
224005/ 4478/IDeg/ 4[redacted]/Male/3[redacted]	2	Underdose/ Underdose/ 1/71	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Underdose: Site prescribed 20 units/ Other: underdose	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
224006/ 4478/IDeg/ 5[redacted]/Female/3[redacted]	1	Underdose/ Wrong dose administered- under dose/ 1/66	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Underdose: 10 units was prescribed. Subject was on Lantus 90 units./ Other: protocol 4478 was confused with the other onwards protocols, therefore the low randomization doses were in error	Hypo no. : NA AE no. : NA
224007/ 4478/IDeg/ 5[redacted]/Female/3[redacted]	1	Underdose/ Wrong dose administered- under dose./ 1/66	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Underdose: Protocol 4478 was confused with the other Onwards protocols, therefore the low randomization doses were in error/ Other: protocol 4478 was confused with the other onwards protocols, therefore the low randomization doses were in error	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")

Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
951002/ 4479/Ico/ 4[redacted]/Male/3[redacted]	1	Drug abuse/ Dose abuse/ 8/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: The patient was confused and administered 30U more than the prescribed dose./ Distraction	Hypo no. : NA AE no. : NA
951002/ 4479/Ico/ 4[redacted]/Male/3[redacted]	2	Headache/ Headache/ 44/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Underdose: The patient got confused and administered 3U less than the prescribed dose/ Distraction	Hypo no. : NA AE no. : NA
951002/ 4479/Ico/ 4[redacted]/Male/3[redacted]	3	Headache/ Episodic headache/ 101/7	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Overdose: the patient was applying 59UI instead of 56UI/ Distraction	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
954006/ 4479/Ico/ 5[redacted]/Male/2[redacted]	4	Medication error/ Medication error (dose)- under dose/ 127/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong frequency of administration: Lower frequency: Applied 210IU instead of 230IU/ Distraction	Hypo no. : NA AE no. : NA
954015/ 4479/Ico/ 5[redacted]/Male/3[redacted]	2	Medication error/ Medication error (dose) applied a 20 iu dose instead of a 44 iu dose because her degludec/ placebo pen had run out and was not replenished/ 92/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Underdose: Applied 20 IU instead of 44 IU/ Other: applied a 20 iu dose instead of a 44 iu dose because her degludec/placebo pen had run out and was not replenished	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
102001/ 4479/IDeg/ 6[redacted]/Female/2[redacted]	1	Intentional product use issue/ Intentional dosage reduction/ 89/14	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Underdose: The exact dose reduction is not known/ Other: during the group period, the patient voluntarily went to other hospitals to prescribe chinese herbal medicine hypoglycemia, and deliberately reduced the amount of test drugs	Hypo no. : NA AE no. : NA
	1	Intentional product use issue/ Intentional dosage reduction/ 89/14	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Underdose: The exact dose reduction is not known/ Other: during the group period, the patient voluntarily went to other hospitals to prescribe chinese herbal medicine hypoglycemia, and deliberately reduced the amount of test drugs	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
106021/ 4479/IDeg/ 7[redacted]/Male/2[redacted]	1	Wrong product administered/ Accidental wrong product administered/ 72/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong products administered/used: Other: INSULIN ICODEC/ PLACEBO INSTEAD OF INSULIN DEGLUDEC/ PLACEBO/ Distraction	Hypo no. : NA AE no. : NA
107001/ 4479/IDeg/ 5[redacted]/Female/2[redacted]	1	Medication error/ Medication errors (study drugs)/ 2/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong products administered/used: Other: INSULIN ICODEC/ PLACEBO INSTEAD OF INSULIN DEGLUDEC/ PLACEBO/ Mix-up of products	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
307001/ 4479/IDeg/ 7[redacted]/Female/3[redacted]	1	Incorrect dose administered/ Dose not administered due to medication error/ 29/99	Non-serious/ Moderate/ Recovered/ resolved	Placebo	Other: Dose not administered as needle never penetrated the skin./ Misunderstanding of training/verbal instruction	Hypo no. : NA AE no. : NA
	1	Incorrect dose administered/ Dose not administered due to medication error/ 29/99	Non-serious/ Moderate/ Recovered/ resolved	IDeg	Other: Dose not administered as needle never penetrated the skin./ Misunderstanding of training/verbal instruction	Hypo no. : NA AE no. : NA
951004/ 4479/IDeg/ 5[redacted]/Male/3[redacted]	3	Overdose/ Dose error (overdose)/ 22/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Overdose: The patient administered one more dose than prescribed on the last visit./ Distraction	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
951007/ 4479/IDeg/ 5[redacted]/Male/2[redacted]	1	Wrong dose/ Wrong dose use/ 10/8	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Underdose: The patient administered lower doses in relation to the prescribed dose at the last visit/ Misunderstanding of instructions for use	Hypo no. : NA AE no. : NA
951010/ 4479/IDeg/ 4[redacted]/Female/3[redacted]	2	Underdose/ Dose error (underdose)/ 15/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Underdose: The patient applied a lower dose than the prescribed dose./ Distraction	Hypo no. : NA AE no. : NA
951015/ 4479/IDeg/ 5[redacted]/Male/2[redacted]	1	Wrong dose/ Wrong use of ip (subdose)/ 10/5	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Underdose: The patient applied a lower dose of 3 U in relation to the prescribed dose in 3 days and did not apply the dose in 2 days./ For psychological effect	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
953012/ 4479/IDeg/ 4[redacted]/Male/2[redacted]	1	Incorrect dose administered/ Medication error degludec/ placebo - wrong dose administered-underdose/ 21/1	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong dose administered: Underdose: 15U instead of 16U/ Distraction	Hypo no. : NA AE no. : NA
953012/ 4479/IDeg/ 4[redacted]/Male/2[redacted]	2	Incorrect dose administered/ Medication error icodec/ placebo - wrong dose administered-overdose/ 57/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Overdose: 210U instead of 230U/ Distraction	Hypo no. : NA AE no. : NA
953022/ 4479/IDeg/ 4[redacted]/Male/2[redacted]	2	Incorrect dose administered/ Wrong dose administered-underdose icodec/placebo/ 36/1	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Underdose: By mistake patient applied 150U when he should have applied 170U/ Distraction	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
954013/ 4479/IDeg/ 6[redacted]/Male/2[redacted]	4	Extra dose administered/ Medication error (extra dose) mistakenly applied twice the dose of icodec/ placebo/ 133/2	Non-serious/ Mild/ Recovered/ resolved	Placebo	Wrong dose administered: Underdose: Mistakenly applied twice the dose of icodec/placebo/ Distraction	Hypo no. : NA AE no. : NA
102014/ 4480/Ico/ 7[redacted]/Female/3[redacted]	3	Overdose/ Wrong dose administered, overdose/ 148/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: OVERDOSE/ Distraction	Hypo no. : 21, 22, 23 AE no. : NA
301005/ 4480/Ico/ 6[redacted]/Male/3[redacted]	1	Incorrect dose administered/ Wrong dose of administration./ 2/7	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong frequency of administration: Higher frequency: HIGHER FREQUENCY/ Other: human mistake	Hypo no. : 9 AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
311015/ 4480/Ico/ 7[redacted]/Male/3[redacted]	2	Accidental overdose/ Medication error (introduced a dose greater than prescribed, erroneously)/ 8/7	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: OVERDOSE/ Distraction	Hypo no. : NA AE no. : NA
404004/ 4480/Ico/ 6[redacted]/Male/3[redacted]	1	Wrong product administered/ Wrong products administered/ 2/3	Non-serious/ Mild/ Recovered/ resolved		Wrong products administered/used: Other: OTHER/ Other: subject stated that he inadvertently took his own personal novolog a few days last week. Subject has been re-counseled by investigator to only use study provided insulin aspart	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
406005/ 4480/Ico/ 7[redacted]/Female/3[redacted]	4	Incorrect dose administered/ Medication error-wrong dose administered/ 106/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: OVERDOSE/ Other: subject had an issues with dun251744 when injecting her basal insulin. Subject states that there was a little insulin that was administered, however subject did not look how much insulin admini	Hypo no. : NA AE no. : NA
414002/ 4480/Ico/ 4[redacted]/Male/3[redacted]	1	Incorrect dose administered/ Subject dose incorrectly/ 8/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: OVERDOSE/ Incorrect handling of product	Hypo no. : NA AE no. : NA
804008/ 4480/Ico/ 6[redacted]/Male/2[redacted]	1	Accidental underdose/ Accidental lower dose of trial product/ 1/7	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Underdose: UNDERDOSE/ Misunderstanding of training/verbal instruction	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
805006/ 4480/Ico/ 5[redacted]/Female/3[redacted]	1	Extra dose administered/ Icodec extradose/ 8/8	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: OVERDOSE/ Distraction	Hypo no. : 3 AE no. : NA
202013/ 4480/IGlar/ 4[redacted]/Female/3[redacted]	3	Accidental overdose/ Accidental administration of higer dose unintentional/ 23/1	Non-serious/ Mild/ Recovered/ resolved	IGlar	Wrong dose administered: Overdose: OVERDOSE/ Distraction	Hypo no. : NA AE no. : NA
202013/ 4480/IGlar/ 4[redacted]/Female/3[redacted]	4	Accidental overdose/ Accidental administration of higer dose unintentional/ 5/1	Non-serious/ Mild/ Recovered/ resolved	IGlar	Wrong dose administered: Overdose: OVERDOSE/ Distraction	Hypo no. : NA AE no. : NA
414001/ 4480/IGlar/ 7[redacted]/Male/3[redacted]	2	Wrong product administered/ Wrong products administered/ 28/43	Non-serious/ Mild/ Recovered/ resolved	IGlar	Wrong products administered/used: Other: OTHER/ Mix-up of products	Hypo no. : 7 AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
421001/ 4480/IGlar/ 6[redacted]/Male/2[redacted]	5	Accidental overdose/ Medication error-accidental overdose/ 62/2	Non-serious/ Mild/ Recovered/ resolved	IGlar	Wrong dose administered: Overdose: OVERDOSE/ Other: needle bent upon insertion into skin and medication was leaked onto abdomen. Subject unsure of dosed amount and gave an additional half dose.	Hypo no. : 15 AE no. : NA
429004/ 4480/IGlar/ 6[redacted]/Male/2[redacted]	1	Product administration error/ Accidental multiple drug administration/ 38/1	Non-serious/ Mild/ Recovered/ resolved	IGlar	Wrong products administered/used: Other: OTHER/ Mix-up of products	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")

Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
431013/ 4480/IGlar/ 5[redacted]/Male/3[redacted]	1	Incorrect dose administered/ Medication error-wrong dose administered/ 35/1	Non-serious/ Mild/ Recovered/ resolved		Wrong dose administered: Overdose: OVERDOSE/ Other: patient was tired and accidentally dialed up the incorrect dose for aspart insulin (instead of 10 units he administered 45 units which is his prescribed dose of glargine).	Hypo no. : NA AE no. : NA
431013/ 4480/IGlar/ 5[redacted]/Male/3[redacted]	2	Incorrect dose administered/ Medication error-wrong frequency of administration/ 93/1	Non-serious/ Mild/ Recovered/ resolved		Wrong frequency of administration: Higher frequency: HIGHER FREQUENCY/ Distraction	Hypo no. : 14, 19 AE no. : NA
803001/ 4480/IGlar/ 6[redacted]/Male/3[redacted]	2	Medication error/ Medication error/ 143/1	Non-serious/ Mild/ Recovered/ resolved		Wrong dose administered: Overdose: OVERDOSE/ Other: due to a connection error new prescription wasn't received by patient	Hypo no. : 29 AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")

Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
205028/ 4481/Ico/ 6[redacted]/Female/1[redacted]	1	Accidental overdose/ Overdose of insulin icodec-dosed 90u twice- accidental overdose/ 71/15	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong frequency of administration: Higher frequency: Overdose (180U)/ Other: due to forgetting	Hypo no. : 1, 2, 3, 4 AE no. : NA
204002/ 4481/OD analogues/ 4[redacted]/Female/2[redacted]	1	Incorrect dose administered/ Medication error, given dose 32u instead of intended dose 28u by accident/ 99/1	Non-serious/ Mild/ Recovered/ resolved	OD analogues	Wrong dose administered: Overdose: subject administered 32 U instead of 28U./ Dispensing error	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")

Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
206001/ 4481/OD analogues/ 5[redacted]/Male/3[redacted]	1	Product administration error/ The patient tried to apply the insulin degludec without opening the cover of the insulin pen (due to misunderstanding)/ 2/91	Non-serious/ Mild/ Recovered/ resolved	OD analogues	Wrong route of administration: Other: wrong route of administration (the patient tried to apply the insulin degludec without opening the cover of the insulin pen)/ Misunderstanding of training/verbal instruction	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
104002/ 4625/Ico/ 5[redacted]/Male/3[redacted]	1	Accidental overdose/ Medication error by subject 370 units of ip injected prior to his appointment instead of at office. He overdosed/ 8/2	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong frequency of administration: Higher frequency: Subject self administered 370 U of icodec the night before V3. Therefore, V3 180 u of icodec is on hold. Subject did not follow instructions/protocol/ Other: error by subject. Subject injected 370 u icodec the night before visit 3 of july 29. Subject did not follow protocol instructions. V3 dose for icodec should be 180 u as per protocol is now on h	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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201001/ 4625/Ico/ 6[redacted]/Male/2[redacted]	2	Incorrect dose administered/ Loading dose error due to preexsisting insulin toujeo ip dose was used due to protocol too high ip 340 e/ 1/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: icodec 340 instead of 240/ Misunderstanding of instructions for use	Hypo no. : NA AE no. : NA
203003/ 4625/Ico/ 4[redacted]/Female/2[redacted]	1	Product administration error/ Excess carbohydrate intake to prevent hypoglycemia due to double-dose injection of basal insulin/ 143/4	Serious/ Severe/ Recovered/ resolved	Ico	Wrong frequency of administration: Higher frequency: icodec administered on Friday 4th and Saturday 5th March 2022/ Distraction	Hypo no. : NA AE no. : NA
252006/ 4625/Ico/ 2[redacted]/Female/2[redacted]	1	Prescribed overdose/ Overdose, 130 units instead of 70 (bad prescription)/ 8/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: 130 units instead 70 units/ Miscalculation	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
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Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
252007/ 4625/Ico/ 2[redacted]/Female/2[redacted]	1	Prescribed overdose/ Overdose 200 units instead of 150 (bad prescription)/ 7/1	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: 200 units instead of 150 units/ Miscalculation	Hypo no. : NA AE no. : NA
304001/ 4625/Ico/ 6[redacted]/Male/3[redacted]	1	Prescribed overdose/ Overdose as there was a medication error. Intended dose was 150 but prescribed 170 and participant administered. Appropriate advice given and monitored/ 8/8	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: pt prescribed and administered 170 units of icodec instead of 100 units/ Miscalculation	Hypo no. : 4 AE no. : NA
305002/ 4625/Ico/ 5[redacted]/Male/2[redacted]	1	Prescribed overdose/ Overdose of basal insulin at visit 2 initial loading dose was prescribed wrongly as 560u rather than 420u./ 1/15	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: He was given 560U instead of 420U/ Miscalculation	Hypo no. : 1 AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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305004/ 4625/Ico/ 5[redacted]/Male/2[redacted]	1	Prescribed overdose/ Overdose of basal insulin visit 3 18-aug-2021- the initial loading dose 250u was not reduced to the intended 170u. Therefore an extra 80u was prescribed wrongly and injected./ 8/22	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: He was given 250U instead of 170U dose./ Other: accidental	Hypo no. : NA AE no. : NA
305005/ 4625/Ico/ 3[redacted]/Female/2[redacted]	1	Accidental overdose/ Accidental overdose. Medication error (visit 3 dose not reduced). Subject assumed incorrectly that she should take the same dose as visit 2 before attending visit 3./ 8/9	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: 250U instead of 130U/ Misunderstanding of instructions for use	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
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Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
501008/ 4625/Ico/ 6[redacted]/Male/3[redacted]	1	Accidental overdose/ Pat. Injected 260 iu of insulin instead of the prescribed 180 iu by accident/ 8/1	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: injected 85 units too much/ Other: patient injected the same does, as in visit 2 without communication at home before visit in the center	Hypo no. : NA AE no. : NA
501009/ 4625/Ico/ 4[redacted]/Male/2[redacted]	1	Accidental overdose/ Patient injected 70 units too much of the medication by accident/ 1/1	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: injected 70 units too much/ Miscalculation	Hypo no. : NA AE no. : NA
504001/ 4625/Ico/ 5[redacted]/Male/2[redacted]	1	Incorrect dose administered/ Wrong dose administered (170 iu instead of 110 iu) due to subject's misunderstanding of training/ 8/1	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: Injection of 170 UI instead of the prescribed 110 IU/ Misunderstanding of training/verbal instruction	Hypo no. : 1 AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

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fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
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Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
506005/ 4625/Ico/ 5[redacted]/Female/2[redacted]	1	Accidental overdose/ Medication error overdose: injected 250 u insulin instead of 190 u by mistake/ 1/6	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: due to increased exercise, the planned insulin dose was too much/ Miscalculation	Hypo no. : NA AE no. : NA
506005/ 4625/Ico/ 5[redacted]/Female/2[redacted]	2	Accidental overdose/ Medication error overdose: injected 230 u insulin instead of 130 u by mistake/ 7/8	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: Insulin dose miscalculation. Unfortunately, the dose was not calculated according to the protocol./ Miscalculation	Hypo no. : 1, 2, 3, 6, 7, 8 AE no. : NA
606005/ 4625/Ico/ 5[redacted]/Male/2[redacted]	2	Accidental overdose/ Accidental misadministration of dose-administered 290u instead of 190u/ 57/1	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: subject administered incorrect dose of 290U rather than the prescribed dose of 190U./ Distraction	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
nn1436/nn1436-iss/submission_20221024_er
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
751005/ 4625/Ico/ 5[redacted]/Male/2[redacted]	1	Accidental overdose/ Accidental overdose v2 basal dose was calculated as considering the total insulin dose (bazal+bollus) according to the protocol by mistake. *See comment*/ 1/28	Non-serious/ Moderate/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: V2 icodec dose was calculated as considering the total insulin dose (basal+bollus) according to the/ Other: v2 icodec dose was calculated as considering the total insulin dose(basal+bollus) according to the protocol by mistake.	Hypo no. : NA AE no. : NA
751005/ 4625/Ico/ 5[redacted]/Male/2[redacted]	2	Product dispensing error/ No adverse event occured but wrong medication given to patient.the patient was invited to the site.wrong medication was taken from the patient. 2939912,2939913,2939914,2939915,2939916(aspart)/ 101/8	Non-serious/ Mild/ Recovered/ resolved	Ico	Other: Dispensing Error/ Dispensing error	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:57:54 - lmederrform/lmederrform.txt

Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
808008/ 4625/Ico/ 4[redacted]/Female/2[redacted]	1	Incorrect dose administered/ Wrong dose administration: dose to be administered according to protocol -200 u, dose assigned by investigator (and administered by patient)-270 u. Reason: wrong titration/ 1/7	Non-serious/ Mild/ Recovered/ resolved	Ico	Wrong dose administered: Overdose: dose to be administered according to protocol -200 U. Dose administered by patient -270 U./ Miscalculation	Hypo no. : NA AE no. : NA
304005/ 4625/IDeg/ 6[redacted]/Male/2[redacted]	1	Wrong product administered/ Participant incidentally gave himself 24 units novorapid instead of tresiba/ 74/1	Non-serious/ Moderate/ Recovered/ resolved	IDeg	Wrong products administered/used: Other: Novorapid 24 units administered by error by participant instead of 24 units tresiba/ Other: novorapid 24 units administered by error by participant instead of 24 units tresiba	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
nn1436/nn1436-iss/submission_20221024_er
05DEC2022:12:57:54 - lmederrform/lmederrform.txt

Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
500001/ 4625/IDeg/ 2[redacted]/Male/2[redacted]	1	Wrong product administered/ Injected 30u bolus insulin instead of 30 u basal insulin by accident (this happened because subject did injection during a sleepover in the dark, so he couldn't see the colour of the pens./ 14/1	Non-serious/ Moderate/ Recovered/ resolved	IDeg	Wrong products administered/used: Other: INSULIN ICODEC/ INSULIN DEGLUDEC/ Mix-up of products	Hypo no. : 5 AE no. : NA
627006/ 4625/IDeg/ 4[redacted]/Female/2[redacted]	4	Wrong product administered/ Medication error- wrong products administered/ 63/1	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong products administered/used: Other: INSULIN ICODEC/ INSULIN DEGLUDEC/ Mix-up of products	Hypo no. : 30, 9 AE no. : NA
627006/ 4625/IDeg/ 4[redacted]/Female/2[redacted]	9	Medication error/ Mixed up of two study medications - basal and bolus insulin/ 161/1	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong products administered/used: Other: INSULIN ICODEC/ INSULIN DEGLUDEC/ Mix-up of products	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
nn1436/nn1436-iss/submission_20221024_er
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
627007/ 4625/IDeg/ 2[redacted]/Male/2[redacted]	1	Wrong product administered/ Medication error: wrong products administered/ 28/1	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong products administered/used: Other: INSULIN ICODEC/ INSULIN DEGLUDEC/ Mix-up of products	Hypo no. : 5 AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"
fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"
suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")
nn1436/nn1436-iss/submission_20221024_er
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Medication errors incl. misuse and abuse - additional data collection - on-treatment/main-on-treatment - listing - safety analysis set

Subject ID/ Trial/Treatment/ Age/Sex/BMI	AE no.	Preferred term/ Reported term/ Study day/Duration (days)	Seriousness/ Severity/ Outcome	Trial product involved	Classification of medication error/ Reason	Hypoglycaemic episodes or AEs due to medication error
628003/ 4625/IDeg/ 5[redacted]/Male/3[redacted]	1	Accidental overdose/ Medication error- accidental overdose- subject took 9 extra unit of long acting insulin. Intended dose was 49/ 61/1	Non-serious/ Mild/ Recovered/ resolved	IDeg	Wrong products administered/used: Other: Subject administered 9 units of Degludec, but instead should have dosed with 9 units of Novolog. Subject inadvertently took more Degludec than de intended dose. Subject dose of Degludec was 49 units/ Other: subject administered 9 units of degludec, but instead should have dosed with 9 units of novolog. Subject inadvertently took more degludec than de intended dose. Subject dose of degludec was 49	Hypo no. : NA AE no. : NA

AE no.: Adverse event number, Age: Age in years at baseline, BMI: Body mass index (kg/m^2) at baseline, Hypo no.: Hypoglycaemic episode number. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. MedDRA version 24.1. OD analogues: Once-daily basal insulin analogues (IDeg, IGlar U100, IGlar U300). Data from ONWARDS 1-6, only main part of ONWARDS 1 and 6.

adae.xpt; variable(s): USUBJID SUBJID STUDYID TRTA AGE SEX BMIBL AEREFID AEDECOD AETERM ASTDT ASTDY ADURN AESER ASEV AOUT ACAT1REA ACAT1AEH; criteria: SAFFL == "Y" & ANL06FL == "Y" & ANELFL == "Y"

fa.xpt; variable(s): FAORRES; criteria: FAOBJ == "ACCIDENTAL MISADMINISTRATION" | FAOBJ == "INTENTIONAL MISADMINISTRATION"

suppfa.xpt; variable(s): QVAL; criteria: QNAM %in% c("MISWPROD", "MISWFRH", "MISWFRL", "MISWDOO", "MISWDOU", "MISWROUT", "MISCLAOT")

7.3.140 Injection site reactions (selected preferred terms) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	34	(1.6)	69	5.15	30	(1.4)	52	2.88
General disorders and administration site conditions								
Injection site reaction	15	(0.7)	29	2.23	6	(0.3)	8	0.46
Injection site pruritus	4	(0.2)	19	1.43	1	(0.0)	1	0.08
Injection site pain	3	(0.1)	3	0.24	13	(0.6)	31	1.67
Injection site erythema	3	(0.1)	5	0.36	4	(0.2)	4	0.19
Injection site bruising	3	(0.1)	3	0.20	5	(0.2)	5	0.26
Injection site swelling	2	(0.1)	2	0.16	1	(0.0)	1	0.08
Injection site hypersensitivity	2	(0.1)	2	0.09	0			
Injection site mass	2	(0.1)	2	0.09	1	(0.0)	1	0.09
Injection site urticaria	1	(0.0)	2	0.19	1	(0.0)	1	0.05
Application site bruise	1	(0.0)	1	0.08	0			
Application site pruritus	1	(0.0)	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.141 Injection site reactions (selected preferred terms) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	33	(1.8)	67	5.73	28	(1.5)	50	3.11
General disorders and administration site conditions								
Injection site reaction	15	(0.8)	29	2.57	6	(0.3)	8	0.53
Injection site pruritus	4	(0.2)	19	1.66	1	(0.1)	1	0.09
Injection site pain	3	(0.2)	3	0.27	12	(0.6)	30	1.82
Injection site erythema	3	(0.2)	5	0.42	4	(0.2)	4	0.22
Injection site bruising	3	(0.2)	3	0.23	5	(0.3)	5	0.30
Injection site swelling	2	(0.1)	2	0.18	1	(0.1)	1	0.09
Injection site hypersensitivity	2	(0.1)	2	0.11	0			
Injection site mass	2	(0.1)	2	0.11	0			
Application site bruise	1	(0.1)	1	0.09	0			
Application site pruritus	1	(0.1)	1	0.09	0			
Injection site urticaria	0				1	(0.1)	1	0.05

%: 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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.

adsl.xpt; variable(s): OTMTDURY; criteria: POOLGR1N == 1 & SAFFL == "Y"
adae.xpt; variable(s): AEBODSYS AEDECOD; criteria: POOLGR1N == 1 & SAFFL == "Y" & (ANELFL) == "Y" & AEDECOD %in% pts_adr_ccso_list[[2]] & (ANL06FL) == "Y"
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7.3.142 Hypersensitivity reactions (selected preferred terms) - adverse events by system organ class and preferred term - on-treatment/main-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	2170				2170			
PYE (years)	1681.23				1680.58			
Events	8	(0.4)	10	0.63	14	(0.6)	14	0.85
Skin and subcutaneous tissue disorders								
Urticaria	7	(0.3)	7	0.45	12	(0.6)	12	0.72
General disorders and administration site conditions								
Swelling face	2	(0.1)	2	0.14	2	(0.1)	2	0.12
Gastrointestinal disorders								
Lip swelling	1	(0.0)	1	0.04	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the on-treatment period or the last planned visit in the main part of the trial. Daily basal insulin: IDeg, IGlar U100, and IGlar U300. Phase 3a pool: ONWARDS 1-6, only main part of ONWARDS 1 and 6. MedDRA version 24.1. Events found via MedDRA queries.

7.3.143 Hypersensitivity reactions (selected preferred terms) - adverse events by system organ class and preferred term - on-treatment/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	1880				1878			
PYE (years)	1538.92				1536.46			
Events	7	(0.4)	9	0.62	11	(0.6)	11	0.65
Skin and subcutaneous tissue disorders								
Urticaria	7	(0.4)	7	0.52	9	(0.5)	9	0.51
Gastrointestinal disorders								
Lip swelling	1	(0.1)	1	0.05	0			
General disorders and administration site conditions								
Swelling face	1	(0.1)	1	0.05	2	(0.1)	2	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. On-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the follow-up visit (FU2), the last date on trial product + 5 weeks for once daily insulin and + 6 weeks for once weekly insulin or the end-date for the in-trial period. Main-on-treatment: Onset date on or after the first dose of trial product and no later than the first date of either the end-date of the 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. MedDRA version 24.1. Events found via MedDRA queries.