## 付録 2.7.4- 30　　Grade 別の有害事象（いずれかの投与群で発現割合 0%超）

### 001 試験＋002 試験＋006 試験＋010 試験

### MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

### Subjects With Adverse Events by Maximum Toxicity Grade
### (Incidence >0% in One or More Treatment Groups)
### PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
### (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Subjects in population | 682 | | 1,232 | | 1,567 | | 2,799 | |
| with one or more adverse events | 661 | (96.9) | 1,192 | (96.8) | 1,535 | (98.0) | 2,727 | (97.4) |
| Grade 1 | 100 | (14.7) | 172 | (14.0) | 242 | (15.4) | 414 | (14.8) |
| Grade 2 | 247 | (36.2) | 452 | (36.7) | 588 | (37.5) | 1,040 | (37.2) |
| Grade 3 | 235 | (34.5) | 440 | (35.7) | 580 | (37.0) | 1,020 | (36.4) |
| Grade 4 | 36 | (5.3) | 66 | (5.4) | 77 | (4.9) | 143 | (5.1) |
| Grade 5 | 43 | (6.3) | 62 | (5.0) | 48 | (3.1) | 110 | (3.9) |
| with no adverse events | 21 | (3.1) | 40 | (3.2) | 32 | (2.0) | 72 | (2.6) |
| **Blood and lymphatic system disorders** | **105** | **(15.4)** | **188** | **(15.3)** | **299** | **(19.1)** | **487** | **(17.4)** |
| Grade 1 | 29 | (4.3) | 54 | (4.4) | 130 | (8.3) | 184 | (6.6) |
| Grade 2 | 50 | (7.3) | 91 | (7.4) | 89 | (5.7) | 180 | (6.4) |
| Grade 3 | 21 | (3.1) | 36 | (2.9) | 72 | (4.6) | 108 | (3.9) |
| Grade 4 | 4 | (0.6) | 6 | (0.5) | 8 | (0.5) | 14 | (0.5) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Anaemia | 66 | (9.7) | 135 | (11.0) | 212 | (13.5) | 347 | (12.4) |
| Grade 1 | 18 | (2.6) | 39 | (3.2) | 71 | (4.5) | 110 | (3.9) |
| Grade 2 | 32 | (4.7) | 69 | (5.6) | 78 | (5.0) | 147 | (5.3) |
| Grade 3 | 14 | (2.1) | 25 | (2.0) | 59 | (3.8) | 84 | (3.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Anaemia of chronic disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune haemolytic anaemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Coagulopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Disseminated intravascular coagulation | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Eosinopenia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eosinophilia | 2 | (0.3) | 2 | (0.2) | 15 | (1.0) | 17 | (0.6) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 14 | (0.9) | 15 | (0.5) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Febrile neutropenia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haemolytic anaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhagic diathesis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypercoagulation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hypercoagulation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Immune thrombocytopenic purpura | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Increased tendency to bruise | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iron deficiency anaemia | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Leukaemoid reaction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Leukocytosis | 5 | (0.7) | 7 | (0.6) | 17 | (1.1) | 24 | (0.9) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 13 | (0.8) | 16 | (0.6) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Leukopenia | 6 | (0.9) | 10 | (0.8) | 12 | (0.8) | 22 | (0.8) |
| Grade 1 | 4 | (0.6) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lymph node pain | 3 | (0.4) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Lymphadenitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphadenopathy | 3 | (0.4) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lymphatic obstruction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphoid tissue hyperplasia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphopenia | 14 | (2.1) | 14 | (1.1) | 19 | (1.2) | 33 | (1.2) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 12 | (0.8) | 15 | (0.5) |
| Grade 2 | 10 | (1.5) | 10 | (0.8) | 2 | (0.1) | 12 | (0.4) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Microcytic anaemia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutropenia | 3 | (0.4) | 7 | (0.6) | 10 | (0.6) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Neutropenia | 3 | (0.4) | 7 | (0.6) | 10 | (0.6) | 17 | (0.6) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutrophilia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Normochromic normocytic anaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pancytopenia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Polycythaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Splenic infarction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Splenomegaly | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombocytopenia | 7 | (1.0) | 15 | (1.2) | 35 | (2.2) | 50 | (1.8) |
| Grade 1 | 3 | (0.4) | 8 | (0.6) | 24 | (1.5) | 32 | (1.1) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 4 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Thrombocytosis | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| **Cardiac disorders** | **55** | **(8.1)** | **109** | **(8.8)** | **144** | **(9.2)** | **253** | **(9.0)** |
| Grade 1 | 15 | (2.2) | 32 | (2.6) | 87 | (5.6) | 119 | (4.3) |
| Grade 2 | 17 | (2.5) | 28 | (2.3) | 22 | (1.4) | 50 | (1.8) |
| Grade 3 | 13 | (1.9) | 32 | (2.6) | 26 | (1.7) | 58 | (2.1) |
| Grade 4 | 4 | (0.6) | 10 | (0.8) | 4 | (0.3) | 14 | (0.5) |
| Grade 5 | 6 | (0.9) | 7 | (0.6) | 5 | (0.3) | 12 | (0.4) |
| Acute coronary syndrome | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Acute myocardial infarction | 2 | (0.3) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Grade 3 | 2 | (0.3) | 5 | (0.4) | 1 | (0.1) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Angina pectoris | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Angina unstable | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Angina unstable | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Aortic valve incompetence | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aortic valve stenosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Arrhythmia | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Arrhythmia supraventricular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Atrial fibrillation | 7 | (1.0) | 16 | (1.3) | 19 | (1.2) | 35 | (1.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 6 | (0.9) | 10 | (0.8) | 6 | (0.4) | 16 | (0.6) |
| Grade 3 | 1 | (0.1) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Atrial flutter | 2 | (0.3) | 7 | (0.6) | 5 | (0.3) | 12 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Atrial thrombosis | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Atrioventricular block complete | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Atrioventricular block first degree | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bradycardia | 2 | (0.3) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bundle branch block left | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bundle branch block right | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Cardiac aneurysm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardiac arrest | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cardiac disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardiac failure | 2 | (0.3) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Cardiac failure congestive | 2 | (0.3) | 5 | (0.4) | 9 | (0.6) | 14 | (0.5) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardiac tamponade | 1 | (0.1) | 6 | (0.5) | 0 | (0.0) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 5 | (0.4) | 0 | (0.0) | 5 | (0.2) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardiac ventricular disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardiac ventricular thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardio-respiratory arrest | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardiogenic shock | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardiomegaly | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardiomyopathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardiopulmonary failure | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Congestive cardiomyopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Coronary artery disease | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cyanosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Left ventricular dysfunction | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Left ventricular failure | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Left ventricular hypertrophy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Mitral valve incompetence | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myocardial infarction | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myocardial ischaemia | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Myocardial ischaemia | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Palpitations | 4 | (0.6) | 7 | (0.6) | 22 | (1.4) | 29 | (1.0) |
| Grade 1 | 3 | (0.4) | 6 | (0.5) | 21 | (1.3) | 27 | (1.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pericardial effusion | 8 | (1.2) | 16 | (1.3) | 11 | (0.7) | 27 | (1.0) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 3 | 4 | (0.6) | 7 | (0.6) | 3 | (0.2) | 10 | (0.4) |
| Grade 4 | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Pericarditis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pericarditis constrictive | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Right ventricular failure | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sinus bradycardia | 1 | (0.1) | 6 | (0.5) | 5 | (0.3) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sinus tachycardia | 4 | (0.6) | 10 | (0.8) | 12 | (0.8) | 22 | (0.8) |
| Grade 1 | 1 | (0.1) | 6 | (0.5) | 11 | (0.7) | 17 | (0.6) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Supraventricular tachycardia | 3 | (0.4) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tachycardia | 10 | (1.5) | 17 | (1.4) | 33 | (2.1) | 50 | (1.8) |
| Grade 1 | 7 | (1.0) | 13 | (1.1) | 28 | (1.8) | 41 | (1.5) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ventricular extrasystoles | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| **Congenital, familial and genetic disorders** | **3** | **(0.4)** | **4** | **(0.3)** | **3** | **(0.2)** | 7 | **(0.3)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Congenital, familial and genetic disorders** | **3** | **(0.4)** | **4** | **(0.3)** | **3** | **(0.2)** | **7** | **(0.3)** |
| Grade 3 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Accessory spleen | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ichthyosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Naevus flammeus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pyloric stenosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Syndactyly | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tracheo-oesophageal fistula | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| **Ear and labyrinth disorders** | **15** | **(2.2)** | **37** | **(3.0)** | **96** | **(6.1)** | **133** | **(4.8)** |
| Grade 1 | 12 | (1.8) | 32 | (2.6) | 83 | (5.3) | 115 | (4.1) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Auricular swelling | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cerumen impaction | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Deafness | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Deafness unilateral | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Ear congestion | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Ear discomfort | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ear haemorrhage | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Ear pain | 1 | (0.1) | 3 | (0.2) | 25 | (1.6) | 28 | (1.0) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 22 | (1.4) | 24 | (0.9) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Ear pruritus | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Ear pruritus | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Ear swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| External ear inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| External ear pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hearing impaired | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hyperacusis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypoacusis | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Middle ear inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Motion sickness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Otorrhoea | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tinnitus | 5 | (0.7) | 9 | (0.7) | 13 | (0.8) | 22 | (0.8) |
| Grade 1 | 4 | (0.6) | 8 | (0.6) | 12 | (0.8) | 20 | (0.7) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vertigo | 5 | (0.7) | 13 | (1.1) | 34 | (2.2) | 47 | (1.7) |
| Grade 1 | 2 | (0.3) | 9 | (0.7) | 30 | (1.9) | 39 | (1.4) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vertigo positional | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vestibular disorder | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Endocrine disorders** | **83** | **(12.2)** | **136** | **(11.0)** | **199** | **(12.7)** | **335** | **(12.0)** |
| Grade 1 | 37 | (5.4) | 48 | (3.9) | 59 | (3.8) | 107 | (3.8) |
| Grade 2 | 42 | (6.2) | 80 | (6.5) | 122 | (7.8) | 202 | (7.2) |
| Grade 3 | 4 | (0.6) | 8 | (0.6) | 16 | (1.0) | 24 | (0.9) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Adrenal haemorrhage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Adrenal haemorrhage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Adrenal insufficiency | 5 | (0.7) | 9 | (0.7) | 11 | (0.7) | 20 | (0.7) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 3 | (0.4) | 6 | (0.5) | 3 | (0.2) | 9 | (0.3) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Adrenocortical insufficiency acute | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune thyroiditis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Cushingoid | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Endocrine disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Goitre | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hyperparathyroidism | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hyperthyroidism | 32 | (4.7) | 43 | (3.5) | 53 | (3.4) | 96 | (3.4) |
| Grade 1 | 22 | (3.2) | 28 | (2.3) | 42 | (2.7) | 70 | (2.5) |
| Grade 2 | 9 | (1.3) | 13 | (1.1) | 9 | (0.6) | 22 | (0.8) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Hypogonadism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypoparathyroidism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypophysitis | 0 | (0.0) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypopituitarism | 2 | (0.3) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Hypothalamo-pituitary disorder | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypothyroidism | 56 | (8.2) | 98 | (8.0) | 138 | (8.8) | 236 | (8.4) |
| Grade 1 | 21 | (3.1) | 28 | (2.3) | 32 | (2.0) | 60 | (2.1) |
| Grade 2 | 35 | (5.1) | 69 | (5.6) | 104 | (6.6) | 173 | (6.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Myxoedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Primary hypothyroidism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Secondary adrenocortical insufficiency | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroiditis | 2 | (0.3) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| **Eye disorders** | **63** | **(9.2)** | **113** | **(9.2)** | **245** | **(15.6)** | **358** | **(12.8)** |
| Grade 1 | 49 | (7.2) | 91 | (7.4) | 187 | (11.9) | 278 | (9.9) |
| Grade 2 | 11 | (1.6) | 19 | (1.5) | 50 | (3.2) | 69 | (2.5) |
| Grade 3 | 3 | (0.4) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Abnormal sensation in eye | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Altered visual depth perception | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Asthenopia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Blepharitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blepharospasm | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blindness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blindness unilateral | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cataract | 6 | (0.9) | 10 | (0.8) | 12 | (0.8) | 22 | (0.8) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Chalazion | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Ciliary muscle spasm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Conjunctival haemorrhage | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Conjunctival hyperaemia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Conjunctivitis allergic | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Conjunctivitis allergic | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Corneal irritation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Corneal pigmentation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diabetic retinopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diplopia | 2 | (0.3) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dry age-related macular degeneration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dry eye | 11 | (1.6) | 15 | (1.2) | 34 | (2.2) | 49 | (1.8) |
| Grade 1 | 9 | (1.3) | 13 | (1.1) | 32 | (2.0) | 45 | (1.6) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Ectropion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eczema eyelids | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Entropion | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erythema of eyelid | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Eye discharge | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Eye disorder | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Eye haemorrhage | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eye inflammation | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye irritation | 3 | (0.4) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Eye movement disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye oedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eye pain | 4 | (0.6) | 4 | (0.3) | 12 | (0.8) | 16 | (0.6) |
| Grade 1 | 4 | (0.6) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Eye pain | 4 | (0.6) | 4 | (0.3) | 12 | (0.8) | 16 | (0.6) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye pruritus | 0 | (0.0) | 2 | (0.2) | 13 | (0.8) | 15 | (0.5) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 11 | (0.7) | 13 | (0.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Eye swelling | 0 | (0.0) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Eyelash discolouration | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Eyelid cyst | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid exfoliation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid function disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid irritation | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eyelid oedema | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eyelid ptosis | 1 | (0.1) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eyelid rash | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Eyelids pruritus | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Foreign body sensation in eyes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Glaucoma | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Growth of eyelashes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypermetropia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypopigmentation of eyelid | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Intraocular haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iridocyclitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Iritis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratitis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lacrimal gland enlargement | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lacrimation increased | 4 | (0.6) | 6 | (0.5) | 15 | (1.0) | 21 | (0.8) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 14 | (0.9) | 18 | (0.6) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Macular degeneration | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ocular discomfort | 2 | (0.3) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ocular hyperaemia | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 8 | (0.5) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ophthalmoplegia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Optic neuropathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Papilloedema | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Periorbital oedema | 0 | (0.0) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Photophobia | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Photopsia | 3 | (0.4) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pupils unequal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Retinal detachment | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Retinal exudates | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Retinal haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Retinal haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Retinal pigment epitheliopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Retinal tear | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Retinal vein occlusion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Scintillating scotoma | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Scleral hyperaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Scleritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Uveitis | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Vision blurred | 15 | (2.2) | 23 | (1.9) | 48 | (3.1) | 71 | (2.5) |
| Grade 1 | 14 | (2.1) | 21 | (1.7) | 39 | (2.5) | 60 | (2.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Visual acuity reduced | 1 | (0.1) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Visual impairment | 5 | (0.7) | 9 | (0.7) | 30 | (1.9) | 39 | (1.4) |
| Grade 1 | 5 | (0.7) | 9 | (0.7) | 26 | (1.7) | 35 | (1.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Vitreous detachment | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vitreous floaters | 5 | (0.7) | 9 | (0.7) | 9 | (0.6) | 18 | (0.6) |
| Grade 1 | 5 | (0.7) | 9 | (0.7) | 8 | (0.5) | 17 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Xerophthalmia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Gastrointestinal disorders** | **354** | **(51.9)** | **657** | **(53.3)** | **1,048** | **(66.9)** | **1,705** | **(60.9)** |
| Grade 1 | 209 | (30.6) | 394 | (32.0) | 610 | (38.9) | 1,004 | (35.9) |
| Grade 2 | 103 | (15.1) | 187 | (15.2) | 282 | (18.0) | 469 | (16.8) |
| Grade 3 | 41 | (6.0) | 73 | (5.9) | 149 | (9.5) | 222 | (7.9) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 5 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Abdominal discomfort | 8 | (1.2) | 13 | (1.1) | 36 | (2.3) | 49 | (1.8) |
| Grade 1 | 5 | (0.7) | 9 | (0.7) | 36 | (2.3) | 45 | (1.6) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Abdominal discomfort | 8 | (1.2) | 13 | (1.1) | 36 | (2.3) | 49 | (1.8) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Abdominal distension | 8 | (1.2) | 24 | (1.9) | 59 | (3.8) | 83 | (3.0) |
| Grade 1 | 8 | (1.2) | 21 | (1.7) | 46 | (2.9) | 67 | (2.4) |
| Grade 2 | 0 | (0.0) | 3 | (0.2) | 12 | (0.8) | 15 | (0.5) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal mass | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal pain | 38 | (5.6) | 83 | (6.7) | 191 | (12.2) | 274 | (9.8) |
| Grade 1 | 27 | (4.0) | 50 | (4.1) | 116 | (7.4) | 166 | (5.9) |
| Grade 2 | 8 | (1.2) | 25 | (2.0) | 56 | (3.6) | 81 | (2.9) |
| Grade 3 | 3 | (0.4) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal pain lower | 3 | (0.4) | 5 | (0.4) | 12 | (0.8) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Abdominal pain upper | 21 | (3.1) | 36 | (2.9) | 79 | (5.0) | 115 | (4.1) |
| Grade 1 | 13 | (1.9) | 23 | (1.9) | 62 | (4.0) | 85 | (3.0) |
| Grade 2 | 7 | (1.0) | 11 | (0.9) | 15 | (1.0) | 26 | (0.9) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Abdominal rigidity | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal tenderness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Acquired oesophageal web | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aerophagia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Anal fissure | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Anal fistula | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Anal haemorrhage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Anal pruritus | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Anorectal disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aphthous stomatitis | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Aphthous stomatitis | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Aptyalism | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Ascites | 5 | (0.7) | 10 | (0.8) | 20 | (1.3) | 30 | (1.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 3 | 2 | (0.3) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Auriculotemporal syndrome | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Autoimmune colitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune pancreatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Barrett's oesophagus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breath odour | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Chapped lips | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cheilitis | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Chronic gastritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Colitis | 6 | (0.9) | 13 | (1.1) | 33 | (2.1) | 46 | (1.6) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 3 | 4 | (0.6) | 9 | (0.7) | 21 | (1.3) | 30 | (1.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Colitis microscopic | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Constipation | 105 | (15.4) | 193 | (15.7) | 304 | (19.4) | 497 | (17.8) |
| Grade 1 | 76 | (11.1) | 142 | (11.5) | 222 | (14.2) | 364 | (13.0) |
| Grade 2 | 25 | (3.7) | 45 | (3.7) | 76 | (4.9) | 121 | (4.3) |
| Grade 3 | 3 | (0.4) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Defaecation urgency | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dental caries | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Dental caries | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Diarrhoea | 95 | (13.9) | 189 | (15.3) | 436 | (27.8) | 625 | (22.3) |
| Grade 1 | 69 | (10.1) | 139 | (11.3) | 327 | (20.9) | 466 | (16.6) |
| Grade 2 | 23 | (3.4) | 43 | (3.5) | 80 | (5.1) | 123 | (4.4) |
| Grade 3 | 3 | (0.4) | 7 | (0.6) | 29 | (1.9) | 36 | (1.3) |
| Diverticulitis intestinal haemorrhagic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diverticulum | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diverticulum gastric | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dry mouth | 22 | (3.2) | 39 | (3.2) | 103 | (6.6) | 142 | (5.1) |
| Grade 1 | 15 | (2.2) | 29 | (2.4) | 94 | (6.0) | 123 | (4.4) |
| Grade 2 | 6 | (0.9) | 9 | (0.7) | 9 | (0.6) | 18 | (0.6) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Duodenal ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Duodenitis | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Duodenogastric reflux | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dyspepsia | 11 | (1.6) | 19 | (1.5) | 46 | (2.9) | 65 | (2.3) |
| Grade 1 | 7 | (1.0) | 13 | (1.1) | 33 | (2.1) | 46 | (1.6) |
| Grade 2 | 4 | (0.6) | 6 | (0.5) | 13 | (0.8) | 19 | (0.7) |
| Dysphagia | 22 | (3.2) | 33 | (2.7) | 26 | (1.7) | 59 | (2.1) |
| Grade 1 | 11 | (1.6) | 18 | (1.5) | 10 | (0.6) | 28 | (1.0) |
| Grade 2 | 6 | (0.9) | 10 | (0.8) | 14 | (0.9) | 24 | (0.9) |
| Grade 3 | 5 | (0.7) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Enteritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Enterocolitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Epigastric discomfort | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Erosive duodenitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eructation | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Faecal incontinence | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Faecal incontinence | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Faecal volume increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Faecaloma | 3 | (0.4) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Faeces discoloured | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Faeces hard | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Faeces pale | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Faeces soft | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Femoral hernia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Flatulence | 2 | (0.3) | 7 | (0.6) | 27 | (1.7) | 34 | (1.2) |
| Grade 1 | 2 | (0.3) | 7 | (0.6) | 25 | (1.6) | 32 | (1.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Food poisoning | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Frequent bowel movements | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastric disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastric haemorrhage | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastric perforation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastric ulcer haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastritis | 4 | (0.6) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Gastritis erosive | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal disorder | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Gastrointestinal disorder | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastrointestinal haemorrhage | 0 | (0.0) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Gastrointestinal pain | 1 | (0.1) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Gastrointestinal perforation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal sounds abnormal | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Gastrointestinal ulcer | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Gastrooesophageal reflux disease | 13 | (1.9) | 30 | (2.4) | 43 | (2.7) | 73 | (2.6) |
| Grade 1 | 7 | (1.0) | 18 | (1.5) | 34 | (2.2) | 52 | (1.9) |
| Grade 2 | 6 | (0.9) | 12 | (1.0) | 9 | (0.6) | 21 | (0.8) |
| Gingival bleeding | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Gingival pain | 0 | (0.0) | 0 | (0.0) | 8 | (0.5) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 8 | (0.5) | 8 | (0.3) |
| Gingival swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Glossitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Glossodynia | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haematemesis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haematochezia | 0 | (0.0) | 0 | (0.0) | 11 | (0.7) | 11 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhoidal haemorrhage | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Haemorrhoids | 3 | (0.4) | 5 | (0.4) | 12 | (0.8) | 17 | (0.6) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Haemorrhoids | 3 | (0.4) | 5 | (0.4) | 12 | (0.8) | 17 | (0.6) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Haemorrhoids thrombosed | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hiatus hernia | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperchlorhydria | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hypoaesthesia oral | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Ileus | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Impaired gastric emptying | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Inguinal hernia | 1 | (0.1) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intestinal obstruction | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Intestinal perforation | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intussusception | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Irritable bowel syndrome | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Large intestinal obstruction | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Large intestinal ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Large intestine perforation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Large intestine perforation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Large intestine polyp | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Leukoplakia oral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip blister | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip dry | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Lip oedema | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Lip pain | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lip pruritus | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lip swelling | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip ulceration | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Loose tooth | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Lower gastrointestinal haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malabsorption | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Melaena | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mouth haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mouth ulceration | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Mucous stools | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Nausea | 139 | (20.4) | 247 | (20.0) | 438 | (28.0) | 685 | (24.5) |
| Grade 1 | 109 | (16.0) | 194 | (15.7) | 332 | (21.2) | 526 | (18.8) |
| Grade 2 | 21 | (3.1) | 39 | (3.2) | 87 | (5.6) | 126 | (4.5) |
| Grade 3 | 9 | (1.3) | 14 | (1.1) | 19 | (1.2) | 33 | (1.2) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Noninfective gingivitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Obstruction gastric | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Odynophagia | 2 | (0.3) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oesophageal obstruction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Oesophageal pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Oesophageal stenosis | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Oesophageal ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oesophagitis | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Oral discomfort | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Oral disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral mucosal blistering | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral mucosal discolouration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral mucosal erythema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral pain | 2 | (0.3) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Painful defaecation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Palatal disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pancreatitis | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Pancreatitis acute | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pancreatitis chronic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pancreatitis chronic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Paraesthesia oral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peptic ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Periodontal disease | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Peritoneal haemorrhage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Post-tussive vomiting | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Proctalgia | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Proctitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rectal haemorrhage | 3 | (0.4) | 8 | (0.6) | 9 | (0.6) | 17 | (0.6) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rectal polyp | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rectal tenesmus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Reflux gastritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Regurgitation | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Retching | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Retroperitoneal haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Saliva altered | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Salivary gland disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Salivary hypersecretion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sensitivity of teeth | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Small intestinal obstruction | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Small intestinal perforation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Splenic artery aneurysm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stomatitis | 30 | (4.4) | 41 | (3.3) | 18 | (1.1) | 59 | (2.1) |
| Grade 1 | 22 | (3.2) | 32 | (2.6) | 16 | (1.0) | 48 | (1.7) |
| Grade 2 | 7 | (1.0) | 8 | (0.6) | 2 | (0.1) | 10 | (0.4) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Stomatitis necrotising | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Subileus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Swollen tongue | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tongue coated | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tongue discolouration | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tongue haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tongue ulceration | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tooth demineralisation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth disorder | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth impacted | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tooth loss | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Toothache | 6 | (0.9) | 10 | (0.8) | 12 | (0.8) | 22 | (0.8) |
| Grade 1 | 4 | (0.6) | 8 | (0.6) | 10 | (0.6) | 18 | (0.6) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Umbilical hernia, obstructive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Upper gastrointestinal haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Upper gastrointestinal haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vomiting | 88 | (12.9) | 157 | (12.7) | 230 | (14.7) | 387 | (13.8) |
| Grade 1 | 70 | (10.3) | 126 | (10.2) | 168 | (10.7) | 294 | (10.5) |
| Grade 2 | 12 | (1.8) | 22 | (1.8) | 39 | (2.5) | 61 | (2.2) |
| Grade 3 | 5 | (0.7) | 8 | (0.6) | 23 | (1.5) | 31 | (1.1) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **General disorders and administration site conditions** | **382** | **(56.0)** | **742** | **(60.2)** | **1,116** | **(71.2)** | **1,858** | **(66.4)** |
| Grade 1 | 187 | (27.4) | 359 | (29.1) | 631 | (40.3) | 990 | (35.4) |
| Grade 2 | 140 | (20.5) | 279 | (22.6) | 375 | (23.9) | 654 | (23.4) |
| Grade 3 | 47 | (6.9) | 94 | (7.6) | 91 | (5.8) | 185 | (6.6) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 5 | 7 | (1.0) | 9 | (0.7) | 16 | (1.0) | 25 | (0.9) |
| Adverse drug reaction | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Application site pruritus | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Asthenia | 76 | (11.1) | 132 | (10.7) | 230 | (14.7) | 362 | (12.9) |
| Grade 1 | 40 | (5.9) | 66 | (5.4) | 128 | (8.2) | 194 | (6.9) |
| Grade 2 | 27 | (4.0) | 50 | (4.1) | 84 | (5.4) | 134 | (4.8) |
| Grade 3 | 9 | (1.3) | 16 | (1.3) | 18 | (1.1) | 34 | (1.2) |
| Axillary pain | 4 | (0.6) | 5 | (0.4) | 28 | (1.8) | 33 | (1.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 18 | (1.1) | 19 | (0.7) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Catheter site erythema | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Catheter site haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Catheter site pain | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Catheter site rash | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Chest discomfort | 8 | (1.2) | 13 | (1.1) | 19 | (1.2) | 32 | (1.1) |
| Grade 1 | 8 | (1.2) | 13 | (1.1) | 16 | (1.0) | 29 | (1.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Chest pain | 55 | (8.1) | 95 | (7.7) | 70 | (4.5) | 165 | (5.9) |
| Grade 1 | 32 | (4.7) | 55 | (4.5) | 52 | (3.3) | 107 | (3.8) |
| Grade 2 | 17 | (2.5) | 31 | (2.5) | 14 | (0.9) | 45 | (1.6) |
| Grade 3 | 6 | (0.9) | 9 | (0.7) | 4 | (0.3) | 13 | (0.5) |
| Chills | 16 | (2.3) | 37 | (3.0) | 116 | (7.4) | 153 | (5.5) |
| Grade 1 | 15 | (2.2) | 33 | (2.7) | 108 | (6.9) | 141 | (5.0) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Crepitations | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cyst | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Death | 6 | (0.9) | 8 | (0.6) | 9 | (0.6) | 17 | (0.6) |
| Grade 5 | 6 | (0.9) | 8 | (0.6) | 9 | (0.6) | 17 | (0.6) |
| Device breakage | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Device dislocation | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Device failure | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Device occlusion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Discomfort | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Drug withdrawal syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Early satiety | 1 | (0.1) | 5 | (0.4) | 1 | (0.1) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 5 | (0.4) | 1 | (0.1) | 6 | (0.2) |
| Enanthema | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Exercise tolerance decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Face oedema | 3 | (0.4) | 6 | (0.5) | 5 | (0.3) | 11 | (0.4) |
| Grade 1 | 3 | (0.4) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Facial pain | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Fatigue | 171 | (25.1) | 374 | (30.4) | 670 | (42.8) | 1,044 | (37.3) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Fatigue | 171 | (25.1) | 374 | (30.4) | 670 | (42.8) | 1,044 | (37.3) |
| Grade 1 | 91 | (13.3) | 203 | (16.5) | 436 | (27.8) | 639 | (22.8) |
| Grade 2 | 59 | (8.7) | 134 | (10.9) | 202 | (12.9) | 336 | (12.0) |
| Grade 3 | 20 | (2.9) | 36 | (2.9) | 32 | (2.0) | 68 | (2.4) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Feeling abnormal | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Feeling cold | 3 | (0.4) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Feeling drunk | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Feeling hot | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Feeling jittery | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fibrosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gait disturbance | 1 | (0.1) | 4 | (0.3) | 17 | (1.1) | 21 | (0.8) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 11 | (0.7) | 13 | (0.5) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| General physical health deterioration | 8 | (1.2) | 11 | (0.9) | 19 | (1.2) | 30 | (1.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 6 | (0.9) | 9 | (0.7) | 7 | (0.4) | 16 | (0.6) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Generalised oedema | 3 | (0.4) | 4 | (0.3) | 13 | (0.8) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Granuloma | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hernia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hunger | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperthermia | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hypothermia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Impaired healing | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Implant site inflammation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Implant site pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Inflammation | 2 | (0.3) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Grade 1 | 0 | (0.0) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Inflammatory pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Influenza like illness | 19 | (2.8) | 28 | (2.3) | 84 | (5.4) | 112 | (4.0) |
| Grade 1 | 12 | (1.8) | 20 | (1.6) | 64 | (4.1) | 84 | (3.0) |
| Grade 2 | 7 | (1.0) | 8 | (0.6) | 19 | (1.2) | 27 | (1.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infusion site bruising | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infusion site extravasation | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Infusion site pain | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Infusion site pruritus | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infusion site swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Injection site bruising | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Injection site discomfort | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Injection site extravasation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Injection site haematoma | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Injection site irritation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Injection site pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



C Confidential

# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Injection site reaction | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Local swelling | 0 | (0.0) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Localised oedema | 4 | (0.6) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Grade 1 | 4 | (0.6) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malaise | 24 | (3.5) | 26 | (2.1) | 21 | (1.3) | 47 | (1.7) |
| Grade 1 | 14 | (2.1) | 15 | (1.2) | 14 | (0.9) | 29 | (1.0) |
| Grade 2 | 10 | (1.5) | 10 | (0.8) | 4 | (0.3) | 14 | (0.5) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Mass | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Medical device complication | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Medical device pain | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mucosal discolouration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mucosal dryness | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Mucosal inflammation | 5 | (0.7) | 16 | (1.3) | 22 | (1.4) | 38 | (1.4) |
| Grade 1 | 3 | (0.4) | 12 | (1.0) | 15 | (1.0) | 27 | (1.0) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Multi-organ failure | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Necrosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nodule | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Non-cardiac chest pain | 13 | (1.9) | 20 | (1.6) | 14 | (0.9) | 34 | (1.2) |
| Grade 1 | 7 | (1.0) | 8 | (0.6) | 10 | (0.6) | 18 | (0.6) |
| Grade 2 | 5 | (0.7) | 8 | (0.6) | 3 | (0.2) | 11 | (0.4) |
| Grade 3 | 1 | (0.1) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Oedema | 9 | (1.3) | 25 | (2.0) | 24 | (1.5) | 49 | (1.8) |
| Grade 1 | 7 | (1.0) | 15 | (1.2) | 19 | (1.2) | 34 | (1.2) |
| Grade 2 | 2 | (0.3) | 8 | (0.6) | 3 | (0.2) | 11 | (0.4) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Oedema peripheral | 53 | (7.8) | 113 | (9.2) | 172 | (11.0) | 285 | (10.2) |
| Grade 1 | 37 | (5.4) | 86 | (7.0) | 124 | (7.9) | 210 | (7.5) |
| Grade 2 | 15 | (2.2) | 26 | (2.1) | 38 | (2.4) | 64 | (2.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Pain | 12 | (1.8) | 64 | (5.2) | 58 | (3.7) | 122 | (4.4) |
| Grade 1 | 5 | (0.7) | 21 | (1.7) | 38 | (2.4) | 59 | (2.1) |
| Grade 2 | 3 | (0.4) | 28 | (2.3) | 12 | (0.8) | 40 | (1.4) |
| Grade 3 | 4 | (0.6) | 15 | (1.2) | 8 | (0.5) | 23 | (0.8) |
| Performance status decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Peripheral swelling | 6 | (0.9) | 12 | (1.0) | 32 | (2.0) | 44 | (1.6) |
| Grade 1 | 3 | (0.4) | 7 | (0.6) | 26 | (1.7) | 33 | (1.2) |
| Grade 2 | 3 | (0.4) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Puncture site erythema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pyrexia | 77 | (11.3) | 145 | (11.8) | 212 | (13.5) | 357 | (12.8) |
| Grade 1 | 55 | (8.1) | 105 | (8.5) | 162 | (10.3) | 267 | (9.5) |
| Grade 2 | 17 | (2.5) | 32 | (2.6) | 45 | (2.9) | 77 | (2.8) |
| Grade 3 | 5 | (0.7) | 8 | (0.6) | 5 | (0.3) | 13 | (0.5) |
| Secretion discharge | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Sensation of foreign body | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sensitivity to weather change | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Serositis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Suprapubic pain | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Swelling | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Systemic inflammatory response syndrome | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Temperature intolerance | 2 | (0.3) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thirst | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Thrombosis in device | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vessel puncture site pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Xerosis | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 10 | (0.6) | 13 | (0.5) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| **Hepatobiliary disorders** | **17** | **(2.5)** | **26** | **(2.1)** | **63** | **(4.0)** | **89** | **(3.2)** |
| Grade 1 | 5 | (0.7) | 8 | (0.6) | 17 | (1.1) | 25 | (0.9) |
| Grade 2 | 5 | (0.7) | 9 | (0.7) | 12 | (0.8) | 21 | (0.8) |
| Grade 3 | 6 | (0.9) | 8 | (0.6) | 28 | (1.8) | 36 | (1.3) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Autoimmune hepatitis | 3 | (0.4) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bile duct obstruction | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Bile duct stone | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Biliary dilatation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cholangitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cholecystitis | 0 | (0.0) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Cholecystitis acute | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cholestasis | 4 | (0.6) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Drug-induced liver injury | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Drug-induced liver injury | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gallbladder pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatic failure | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Hepatic function abnormal | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatic pain | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Hepatic steatosis | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hepatitis | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Hepatocellular injury | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hepatomegaly | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatorenal syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatotoxicity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperbilirubinaemia | 0 | (0.0) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Jaundice | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Jaundice cholestatic | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Liver disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumobilia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pneumobilia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Portal hypertension | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Immune system disorders** | **12** | **(1.8)** | **24** | **(1.9)** | **52** | **(3.3)** | **76** | **(2.7)** |
| Grade 1 | 7 | (1.0) | 14 | (1.1) | 35 | (2.2) | 49 | (1.8) |
| Grade 2 | 3 | (0.4) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Allergy to animal | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Anaphylactic reaction | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Anaphylactoid reaction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Atopy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contrast media allergy | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Cytokine release syndrome | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Drug hypersensitivity | 4 | (0.6) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Food allergy | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hypersensitivity | 1 | (0.1) | 8 | (0.6) | 14 | (0.9) | 22 | (0.8) |
| Grade 1 | 1 | (0.1) | 5 | (0.4) | 9 | (0.6) | 14 | (0.5) |
| Grade 2 | 0 | (0.0) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Immune system disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sarcoidosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Seasonal allergy | 4 | (0.6) | 5 | (0.4) | 15 | (1.0) | 20 | (0.7) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Seasonal allergy | 4 | (0.6) | 5 | (0.4) | 15 | (1.0) | 20 | (0.7) |
| Grade 1 | 4 | (0.6) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Serum sickness | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Infections and infestations** | **245** | **(35.9)** | **467** | **(37.9)** | **713** | **(45.5)** | **1,180** | **(42.2)** |
| Grade 1 | 72 | (10.6) | 138 | (11.2) | 296 | (18.9) | 434 | (15.5) |
| Grade 2 | 102 | (15.0) | 221 | (17.9) | 305 | (19.5) | 526 | (18.8) |
| Grade 3 | 60 | (8.8) | 91 | (7.4) | 99 | (6.3) | 190 | (6.8) |
| Grade 4 | 3 | (0.4) | 6 | (0.5) | 5 | (0.3) | 11 | (0.4) |
| Grade 5 | 8 | (1.2) | 11 | (0.9) | 8 | (0.5) | 19 | (0.7) |
| Abdominal wall abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abscess | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Abscess oral | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Acarodermatitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Acute sinusitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Acute tonsillitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Anal abscess | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Appendicitis perforated | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Arthritis bacterial | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Arthritis infective | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Aspergillus infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Asymptomatic bacteriuria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Atypical pneumonia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bacillus bacteraemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bacteraemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Bacteraemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bacterial sepsis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Bacterial vaginosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bacteriuria | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Body tinea | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchitis | 18 | (2.6) | 28 | (2.3) | 37 | (2.4) | 65 | (2.3) |
| Grade 1 | 8 | (1.2) | 11 | (0.9) | 16 | (1.0) | 27 | (1.0) |
| Grade 2 | 9 | (1.3) | 14 | (1.1) | 16 | (1.0) | 30 | (1.1) |
| Grade 3 | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Bronchopneumonia | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Campylobacter infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Candida infection | 2 | (0.3) | 11 | (0.9) | 12 | (0.8) | 23 | (0.8) |
| Grade 1 | 2 | (0.3) | 10 | (0.8) | 7 | (0.4) | 17 | (0.6) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Catheter site infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cellulitis | 1 | (0.1) | 3 | (0.2) | 31 | (2.0) | 34 | (1.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 15 | (1.0) | 17 | (0.6) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 13 | (0.8) | 13 | (0.5) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cellulitis streptococcal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chronic sinusitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clostridium difficile colitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clostridium difficile infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Conjunctivitis | 5 | (0.7) | 9 | (0.7) | 26 | (1.7) | 35 | (1.3) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 15 | (1.0) | 20 | (0.7) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Conjunctivitis viral | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cystitis | 7 | (1.0) | 11 | (0.9) | 15 | (1.0) | 26 | (0.9) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 8 | (0.5) | 10 | (0.4) |
| Grade 2 | 6 | (0.9) | 9 | (0.7) | 7 | (0.4) | 16 | (0.6) |
| Cytomegalovirus colitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatophytosis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Device related infection | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Device related sepsis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diverticulitis | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Ear infection | 0 | (0.0) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Ear infection fungal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Encephalitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Endocarditis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Enterococcal infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Enterocolitis infectious | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erysipelas | 0 | (0.0) | 0 | (0.0) | 15 | (1.0) | 15 | (0.5) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Erythema migrans | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erythrasma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Escherichia bacteraemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Escherichia infection | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Escherichia urinary tract infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye infection | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Febrile infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Folliculitis | 1 | (0.1) | 1 | (0.1) | 14 | (0.9) | 15 | (0.5) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 13 | (0.8) | 13 | (0.5) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Fungal infection | 4 | (0.6) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Fungal oesophagitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Fungal skin infection | 2 | (0.3) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Furuncle | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Gastroenteritis | 2 | (0.3) | 5 | (0.4) | 16 | (1.0) | 21 | (0.8) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Gastroenteritis viral | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastrointestinal infection | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal viral infection | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Genital candidiasis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Genital herpes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Genital infection fungal | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



C Confidential

# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Gingivitis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Helicobacter infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Herpes ophthalmic | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Herpes simplex | 4 | (0.6) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Herpes simplex encephalitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Herpes virus infection | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Herpes zoster | 3 | (0.4) | 8 | (0.6) | 11 | (0.7) | 19 | (0.7) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 3 | (0.4) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hordeolum | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Incision site abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Incision site infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infected cyst | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infected dermal cyst | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Infected seroma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infected skin ulcer | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infection | 3 | (0.4) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Infection parasitic | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infectious colitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infectious pleural effusion | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Infectious pleural effusion | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infective exacerbation of chronic obstructive airways disease | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Influenza | 12 | (1.8) | 18 | (1.5) | 39 | (2.5) | 57 | (2.0) |
| Grade 1 | 4 | (0.6) | 7 | (0.6) | 25 | (1.6) | 32 | (1.1) |
| Grade 2 | 6 | (0.9) | 9 | (0.7) | 13 | (0.8) | 22 | (0.8) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Intervertebral discitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Kidney infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Klebsiella infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Laryngitis | 2 | (0.3) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Lip infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Listeriosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Liver abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lobar pneumonia | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Localised infection | 0 | (0.0) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lower respiratory tract infection | 9 | (1.3) | 28 | (2.3) | 16 | (1.0) | 44 | (1.6) |
| Grade 1 | 5 | (0.7) | 9 | (0.7) | 8 | (0.5) | 17 | (0.6) |
| Grade 2 | 3 | (0.4) | 14 | (1.1) | 8 | (0.5) | 22 | (0.8) |
| Grade 3 | 1 | (0.1) | 5 | (0.4) | 0 | (0.0) | 5 | (0.2) |
| Lower respiratory tract infection viral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lung abscess | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Lung infection | 14 | (2.1) | 27 | (2.2) | 18 | (1.1) | 45 | (1.6) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Lung infection | 14 | (2.1) | 27 | (2.2) | 18 | (1.1) | 45 | (1.6) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 10 | (1.5) | 21 | (1.7) | 12 | (0.8) | 33 | (1.2) |
| Grade 3 | 4 | (0.6) | 6 | (0.5) | 2 | (0.1) | 8 | (0.3) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lyme disease | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymph gland infection | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lymphangitis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Mastitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mediastinitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Meningitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis listeria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Moraxella infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mucosal infection | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Nail bed infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail infection | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nasal herpes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasopharyngitis | 29 | (4.3) | 41 | (3.3) | 141 | (9.0) | 182 | (6.5) |
| Grade 1 | 25 | (3.7) | 33 | (2.7) | 124 | (7.9) | 157 | (5.6) |
| Grade 2 | 4 | (0.6) | 8 | (0.6) | 17 | (1.1) | 25 | (0.9) |
| Nosocomial infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Oesophageal candidiasis | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Onychomycosis | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Ophthalmic herpes zoster | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral candidiasis | 15 | (2.2) | 24 | (1.9) | 18 | (1.1) | 42 | (1.5) |
| Grade 1 | 7 | (1.0) | 12 | (1.0) | 13 | (0.8) | 25 | (0.9) |
| Grade 2 | 8 | (1.2) | 12 | (1.0) | 5 | (0.3) | 17 | (0.6) |
| Oral fungal infection | 2 | (0.3) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Oral herpes | 4 | (0.6) | 6 | (0.5) | 20 | (1.3) | 26 | (0.9) |
| Grade 1 | 4 | (0.6) | 6 | (0.5) | 19 | (1.2) | 25 | (0.9) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral infection | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oropharyngeal candidiasis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Osteomyelitis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Otitis externa | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Otitis media | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Otitis media acute | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Paronychia | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pelvic abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Penile abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Penile infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Perichondritis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Periodontitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Peritonitis bacterial | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pharyngitis | 5 | (0.7) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pharyngitis streptococcal | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pleural infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumocystis jirovecii pneumonia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia | 50 | (7.3) | 89 | (7.2) | 45 | (2.9) | 134 | (4.8) |
| Grade 1 | 3 | (0.4) | 11 | (0.9) | 5 | (0.3) | 16 | (0.6) |
| Grade 2 | 11 | (1.6) | 28 | (2.3) | 16 | (1.0) | 44 | (1.6) |
| Grade 3 | 28 | (4.1) | 40 | (3.2) | 22 | (1.4) | 62 | (2.2) |
| Grade 4 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 5 | 7 | (1.0) | 8 | (0.6) | 2 | (0.1) | 10 | (0.4) |
| Pneumonia bacterial | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia cryptococcal | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia haemophilus | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia influenzal | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia klebsiella | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumonia pneumococcal | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia viral | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Post procedural cellulitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Post procedural infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Postoperative wound infection | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Proteus infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pseudomonas infection | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pseudomonas infection | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pulmonary sepsis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pulpitis dental | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pyelonephritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pyelonephritis acute | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pyopneumothorax | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pyuria | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rash pustular | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory tract infection | 21 | (3.1) | 30 | (2.4) | 11 | (0.7) | 41 | (1.5) |
| Grade 1 | 6 | (0.9) | 8 | (0.6) | 8 | (0.5) | 16 | (0.6) |
| Grade 2 | 10 | (1.5) | 16 | (1.3) | 2 | (0.1) | 18 | (0.6) |
| Grade 3 | 5 | (0.7) | 6 | (0.5) | 1 | (0.1) | 7 | (0.3) |
| Respiratory tract infection viral | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rhinitis | 9 | (1.3) | 19 | (1.5) | 31 | (2.0) | 50 | (1.8) |
| Grade 1 | 8 | (1.2) | 14 | (1.1) | 28 | (1.8) | 42 | (1.5) |
| Grade 2 | 1 | (0.1) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Salmonellosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Scarlet fever | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sepsis | 2 | (0.3) | 5 | (0.4) | 12 | (0.8) | 17 | (0.6) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Septic shock | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Septic shock | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Sialoadenitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sinusitis | 10 | (1.5) | 23 | (1.9) | 52 | (3.3) | 75 | (2.7) |
| Grade 1 | 3 | (0.4) | 7 | (0.6) | 27 | (1.7) | 34 | (1.2) |
| Grade 2 | 7 | (1.0) | 15 | (1.2) | 23 | (1.5) | 38 | (1.4) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Sinusitis bacterial | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin candida | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Skin infection | 1 | (0.1) | 7 | (0.6) | 24 | (1.5) | 31 | (1.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Soft tissue infection | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Spinal cord infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sputum purulent | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Staphylococcal bacteraemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Staphylococcal infection | 1 | (0.1) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Staphylococcal skin infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Streptococcal infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Streptococcal urinary tract infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Subcutaneous abscess | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombophlebitis septic | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Tinea cruris | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tinea infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tinea pedis | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tinea versicolour | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tonsillitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Tooth abscess | 2 | (0.3) | 8 | (0.6) | 7 | (0.4) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tooth infection | 3 | (0.4) | 7 | (0.6) | 10 | (0.6) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Tracheitis | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Trichophytosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tuberculosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tuberculosis gastrointestinal | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper respiratory tract infection | 22 | (3.2) | 66 | (5.4) | 116 | (7.4) | 182 | (6.5) |
| Grade 1 | 9 | (1.3) | 21 | (1.7) | 67 | (4.3) | 88 | (3.1) |
| Grade 2 | 12 | (1.8) | 44 | (3.6) | 47 | (3.0) | 91 | (3.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Urinary tract infection | 25 | (3.7) | 49 | (4.0) | 113 | (7.2) | 162 | (5.8) |
| Grade 1 | 5 | (0.7) | 12 | (1.0) | 40 | (2.6) | 52 | (1.9) |
| Grade 2 | 19 | (2.8) | 35 | (2.8) | 61 | (3.9) | 96 | (3.4) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Urinary tract infection fungal | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary tract infection viral | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urosepsis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Urosepsis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vaginal infection | 3 | (0.4) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Viral infection | 2 | (0.3) | 12 | (1.0) | 14 | (0.9) | 26 | (0.9) |
| Grade 1 | 2 | (0.3) | 8 | (0.6) | 8 | (0.5) | 16 | (0.6) |
| Grade 2 | 0 | (0.0) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Viral pharyngitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Viral rhinitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Viral sinusitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Viral upper respiratory tract infection | 0 | (0.0) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvitis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal candidiasis | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Vulvovaginal mycotic infection | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Wound infection | 0 | (0.0) | 1 | (0.1) | 16 | (1.0) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 8 | (0.5) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Wound sepsis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Yersinia infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Injury, poisoning and procedural complications** | **65** | **(9.5)** | **121** | **(9.8)** | **241** | **(15.4)** | **362** | **(12.9)** |
| Grade 1 | 32 | (4.7) | 67 | (5.4) | 154 | (9.8) | 221 | (7.9) |
| Grade 2 | 23 | (3.4) | 40 | (3.2) | 63 | (4.0) | 103 | (3.7) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Injury, poisoning and procedural complications** | **65** | **(9.5)** | **121** | **(9.8)** | **241** | **(15.4)** | **362** | **(12.9)** |
| Grade 3 | 9 | (1.3) | 13 | (1.1) | 21 | (1.3) | 34 | (1.2) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Accident | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Accidental overdose | 0 | (0.0) | 0 | (0.0) | 12 | (0.8) | 12 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 11 | (0.7) | 11 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ankle fracture | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Arthropod bite | 3 | (0.4) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Back injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Brain herniation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Burns second degree | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chest injury | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chillblains | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clavicle fracture | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Concussion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contrast media reaction | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contusion | 7 | (1.0) | 12 | (1.0) | 22 | (1.4) | 34 | (1.2) |
| Grade 1 | 6 | (0.9) | 11 | (0.9) | 21 | (1.3) | 32 | (1.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Corneal abrasion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ear abrasion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Epicondylitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eschar | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Excoriation | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Eye penetration | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eyelid contusion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Face injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Facial bones fracture | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fall | 6 | (0.9) | 24 | (1.9) | 38 | (2.4) | 62 | (2.2) |
| Grade 1 | 4 | (0.6) | 17 | (1.4) | 25 | (1.6) | 42 | (1.5) |
| Grade 2 | 0 | (0.0) | 4 | (0.3) | 12 | (0.8) | 16 | (0.6) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Femoral neck fracture | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Femur fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fibula fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Foot fracture | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Fracture displacement | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fractured sacrum | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal anastomotic complication | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hand fracture | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Heat stroke | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hip fracture | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Humerus fracture | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Humerus fracture | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Incision site complication | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Incision site haemorrhage | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Incision site oedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Incision site pain | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Incision site pruritus | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Incision site ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Incisional hernia, obstructive | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infusion related reaction | 5 | (0.7) | 15 | (1.2) | 14 | (0.9) | 29 | (1.0) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 2 | 3 | (0.4) | 10 | (0.8) | 9 | (0.6) | 19 | (0.7) |
| Injection related reaction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Joint dislocation | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Joint injury | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Laceration | 0 | (0.0) | 2 | (0.2) | 15 | (1.0) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 12 | (0.8) | 13 | (0.5) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Ligament sprain | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Limb crushing injury | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Limb injury | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip injury | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Lower limb fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Meniscus injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle contusion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle injury | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle rupture | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle strain | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Periorbital contusion | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pneumonitis chemical | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Post procedural complication | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Post procedural discomfort | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Post procedural haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Post procedural haemorrhage | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Post procedural hypothyroidism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Post procedural inflammation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Post procedural urine leak | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Post-traumatic pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Procedural pain | 4 | (0.6) | 6 | (0.5) | 20 | (1.3) | 26 | (0.9) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Radiation necrosis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Radiation pneumonitis | 4 | (0.6) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Radiation pneumonitis | 4 | (0.6) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Radiation proctitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Radiation skin injury | 0 | (0.0) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Radius fracture | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rib fracture | 3 | (0.4) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Scratch | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Seroma | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skeletal injury | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin abrasion | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin wound | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Soft tissue injury | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Spinal compression fracture | 3 | (0.4) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Spinal fracture | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sternal fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stress fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sunburn | 1 | (0.1) | 3 | (0.2) | 12 | (0.8) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 11 | (0.7) | 14 | (0.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Synovial rupture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Tendon rupture | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Thermal burn | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Thoracic vertebral fracture | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tooth fracture | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Toxicity to various agents | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tracheal haemorrhage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Transfusion reaction | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Traumatic intracranial haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Upper limb fracture | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary retention postoperative | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vascular access complication | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Wound | 0 | (0.0) | 0 | (0.0) | 13 | (0.8) | 13 | (0.5) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Wound complication | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Wound decomposition | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Wound haemorrhage | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Wound necrosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Wound secretion | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Wrist fracture | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Wrist fracture | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| **Investigations** | **201** | **(29.5)** | **359** | **(29.1)** | **506** | **(32.3)** | **865** | **(30.9)** |
| Grade 1 | 107 | (15.7) | 209 | (17.0) | 297 | (19.0) | 506 | (18.1) |
| Grade 2 | 62 | (9.1) | 96 | (7.8) | 133 | (8.5) | 229 | (8.2) |
| Grade 3 | 26 | (3.8) | 46 | (3.7) | 64 | (4.1) | 110 | (3.9) |
| Grade 4 | 5 | (0.7) | 7 | (0.6) | 12 | (0.8) | 19 | (0.7) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Activated partial thromboplastin time prolonged | 3 | (0.4) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Alanine aminotransferase | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Alanine aminotransferase increased | 40 | (5.9) | 65 | (5.3) | 107 | (6.8) | 172 | (6.1) |
| Grade 1 | 31 | (4.5) | 48 | (3.9) | 76 | (4.9) | 124 | (4.4) |
| Grade 2 | 4 | (0.6) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| Grade 3 | 5 | (0.7) | 9 | (0.7) | 15 | (1.0) | 24 | (0.9) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Amylase increased | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Anion gap increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aortic bruit | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aspartate aminotransferase | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Aspartate aminotransferase increased | 31 | (4.5) | 61 | (5.0) | 107 | (6.8) | 168 | (6.0) |
| Grade 1 | 15 | (2.2) | 38 | (3.1) | 73 | (4.7) | 111 | (4.0) |
| Grade 2 | 11 | (1.6) | 14 | (1.1) | 19 | (1.2) | 33 | (1.2) |
| Grade 3 | 5 | (0.7) | 8 | (0.6) | 12 | (0.8) | 20 | (0.7) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Aspiration bronchial | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Autoantibody positive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bilirubin conjugated increased | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Biopsy skin | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood acid phosphatase increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood albumin decreased | 2 | (0.3) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood albumin increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood alkaline phosphatase | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood alkaline phosphatase decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood alkaline phosphatase increased | 27 | (4.0) | 51 | (4.1) | 61 | (3.9) | 112 | (4.0) |
| Grade 1 | 14 | (2.1) | 30 | (2.4) | 40 | (2.6) | 70 | (2.5) |
| Grade 2 | 7 | (1.0) | 12 | (1.0) | 14 | (0.9) | 26 | (0.9) |
| Grade 3 | 6 | (0.9) | 9 | (0.7) | 7 | (0.4) | 16 | (0.6) |
| Blood bicarbonate decreased | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood bicarbonate increased | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Blood bilirubin | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood bilirubin decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood bilirubin increased | 6 | (0.9) | 13 | (1.1) | 38 | (2.4) | 51 | (1.8) |
| Grade 1 | 4 | (0.6) | 6 | (0.5) | 16 | (1.0) | 22 | (0.8) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 13 | (0.8) | 15 | (0.5) |
| Grade 3 | 1 | (0.1) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood calcium decreased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood calcium increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Blood chloride decreased | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Blood cholesterol | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood cholesterol decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Blood cholesterol decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood cholesterol increased | 8 | (1.2) | 21 | (1.7) | 32 | (2.0) | 53 | (1.9) |
| Grade 1 | 7 | (1.0) | 18 | (1.5) | 30 | (1.9) | 48 | (1.7) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood corticotrophin decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood corticotrophin increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood cortisol decreased | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood cortisol increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood creatine increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood creatine phosphokinase increased | 2 | (0.3) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood creatinine decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood creatinine increased | 33 | (4.8) | 49 | (4.0) | 59 | (3.8) | 108 | (3.9) |
| Grade 1 | 20 | (2.9) | 29 | (2.4) | 45 | (2.9) | 74 | (2.6) |
| Grade 2 | 12 | (1.8) | 19 | (1.5) | 12 | (0.8) | 31 | (1.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood electrolytes decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood folate decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood follicle stimulating hormone increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood glucose abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood glucose increased | 0 | (0.0) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Blood immunoglobulin G decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood immunoglobulin G increased | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Blood immunoglobulin M decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood iron decreased | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Blood lactate dehydrogenase increased | 3 | (0.4) | 16 | (1.3) | 25 | (1.6) | 41 | (1.5) |
| Grade 1 | 3 | (0.4) | 16 | (1.3) | 20 | (1.3) | 36 | (1.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood lactic acid increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood luteinising hormone decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood luteinising hormone increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood magnesium decreased | 3 | (0.4) | 5 | (0.4) | 1 | (0.1) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Blood magnesium increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood parathyroid hormone increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood phosphorus decreased | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood phosphorus increased | 2 | (0.3) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Blood potassium decreased | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood potassium increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood pressure diastolic increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood pressure increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Blood prolactin increased | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood sodium decreased | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Blood sodium increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood testosterone decreased | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Blood testosterone increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood thyroid stimulating hormone decreased | 1 | (0.1) | 6 | (0.5) | 17 | (1.1) | 23 | (0.8) |
| Grade 1 | 1 | (0.1) | 6 | (0.5) | 14 | (0.9) | 20 | (0.7) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Blood thyroid stimulating hormone increased | 8 | (1.2) | 17 | (1.4) | 20 | (1.3) | 37 | (1.3) |
| Grade 1 | 5 | (0.7) | 13 | (1.1) | 16 | (1.0) | 29 | (1.0) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Blood triglycerides | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood triglycerides increased | 5 | (0.7) | 6 | (0.5) | 22 | (1.4) | 28 | (1.0) |
| Grade 1 | 4 | (0.6) | 5 | (0.4) | 17 | (1.1) | 22 | (0.8) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood urea increased | 4 | (0.6) | 5 | (0.4) | 15 | (1.0) | 20 | (0.7) |
| Grade 1 | 4 | (0.6) | 5 | (0.4) | 15 | (1.0) | 20 | (0.7) |
| Blood uric acid decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood uric acid increased | 8 | (1.2) | 11 | (0.9) | 12 | (0.8) | 23 | (0.8) |
| Grade 1 | 8 | (1.2) | 10 | (0.8) | 12 | (0.8) | 22 | (0.8) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood urine present | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Body temperature | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Body temperature fluctuation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Body temperature increased | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Brain natriuretic peptide increased | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Brain natriuretic peptide increased | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breath sounds abnormal | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| C-reactive protein increased | 10 | (1.5) | 10 | (0.8) | 6 | (0.4) | 16 | (0.6) |
| Grade 1 | 4 | (0.6) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 2 | 6 | (0.9) | 6 | (0.5) | 1 | (0.1) | 7 | (0.3) |
| Carbon dioxide increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardiac murmur | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cardiac murmur functional | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chest X-ray abnormal | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Computerised tomogram thorax abnormal | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cortisol free urine decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Creatinine renal clearance decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Creatinine renal clearance increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrocardiogram QT prolonged | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Electrocardiogram ST segment abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrocardiogram ST segment elevation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Electrocardiogram T wave abnormal | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Electrocardiogram T wave inversion | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Electrocardiogram abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrocardiogram change | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Electrocardiogram change | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrocardiogram low voltage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrocardiogram repolarisation abnormality | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eosinophil count increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Fibrin D dimer increased | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Forced expiratory volume | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Free thyroxine index increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gamma-glutamyltransferase decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gamma-glutamyltransferase increased | 18 | (2.6) | 22 | (1.8) | 32 | (2.0) | 54 | (1.9) |
| Grade 1 | 6 | (0.9) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Grade 2 | 6 | (0.9) | 7 | (0.6) | 10 | (0.6) | 17 | (0.6) |
| Grade 3 | 4 | (0.6) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Grade 4 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| General physical condition abnormal | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Glucose urine | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grip strength decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haematocrit decreased | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Haemoglobin decreased | 3 | (0.4) | 8 | (0.6) | 10 | (0.6) | 18 | (0.6) |
| Grade 1 | 1 | (0.1) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemoglobin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemoglobin urine | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Heart rate increased | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Heart rate irregular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hepatic enzyme increased | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Immunoglobulins increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Inflammatory marker increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| International normalised ratio increased | 1 | (0.1) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Intraocular pressure decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Intraocular pressure test abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lipase | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lipase increased | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Liver function test abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphocyte count decreased | 6 | (0.9) | 12 | (1.0) | 32 | (2.0) | 44 | (1.6) |
| Grade 1 | 0 | (0.0) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 14 | (0.9) | 18 | (0.6) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Lymphocyte count increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Medical observation | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| N-terminal prohormone brain natriuretic peptide increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutrophil count decreased | 5 | (0.7) | 11 | (0.9) | 10 | (0.6) | 21 | (0.8) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Neutrophil count increased | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Nitrite urine present | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nuclear magnetic resonance imaging brain abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Occult blood | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Occult blood positive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oxygen saturation decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Pancreatic enzymes decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pancreatic enzymes increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Platelet count decreased | 4 | (0.6) | 5 | (0.4) | 24 | (1.5) | 29 | (1.0) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 20 | (1.3) | 24 | (0.9) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Platelet count increased | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Prostatic specific antigen increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Protein total decreased | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Protein total increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Protein urine present | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Prothrombin time prolonged | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| QRS axis abnormal | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Quality of life decreased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Red blood cell count decreased | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Thyroglobulin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine decreased | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Thyroxine decreased | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine free decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine free increased | 5 | (0.7) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 1 | 5 | (0.7) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Thyroxine increased | 3 | (0.4) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 1 | 3 | (0.4) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Transaminases increased | 3 | (0.4) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Tri-iodothyronine decreased | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Tri-iodothyronine free decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tri-iodothyronine free increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tri-iodothyronine increased | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Troponin I increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Troponin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urine leukocyte esterase positive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urine output decreased | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vitamin D decreased | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Waist circumference increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Weight decreased | 58 | (8.5) | 107 | (8.7) | 112 | (7.1) | 219 | (7.8) |
| Grade 1 | 38 | (5.6) | 70 | (5.7) | 76 | (4.9) | 146 | (5.2) |
| Grade 2 | 17 | (2.5) | 33 | (2.7) | 32 | (2.0) | 65 | (2.3) |
| Grade 3 | 3 | (0.4) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Weight increased | 5 | (0.7) | 21 | (1.7) | 49 | (3.1) | 70 | (2.5) |
| Grade 1 | 4 | (0.6) | 14 | (1.1) | 35 | (2.2) | 49 | (1.8) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Weight increased | 5 | (0.7) | 21 | (1.7) | 49 | (3.1) | 70 | (2.5) |
| Grade 2 | 1 | (0.1) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| White blood cell count decreased | 3 | (0.4) | 12 | (1.0) | 16 | (1.0) | 28 | (1.0) |
| Grade 1 | 1 | (0.1) | 8 | (0.6) | 8 | (0.5) | 16 | (0.6) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| White blood cell count increased | 1 | (0.1) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| White blood cells urine | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Metabolism and nutrition disorders** | **266** | **(39.0)** | **505** | **(41.0)** | **604** | **(38.5)** | **1,109** | **(39.6)** |
| Grade 1 | 132 | (19.4) | 259 | (21.0) | 295 | (18.8) | 554 | (19.8) |
| Grade 2 | 76 | (11.1) | 149 | (12.1) | 173 | (11.0) | 322 | (11.5) |
| Grade 3 | 51 | (7.5) | 86 | (7.0) | 114 | (7.3) | 200 | (7.1) |
| Grade 4 | 7 | (1.0) | 11 | (0.9) | 21 | (1.3) | 32 | (1.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Acidosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cachexia | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cell death | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cow's milk intolerance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Decreased appetite | 168 | (24.6) | 310 | (25.2) | 320 | (20.4) | 630 | (22.5) |
| Grade 1 | 99 | (14.5) | 186 | (15.1) | 213 | (13.6) | 399 | (14.3) |
| Grade 2 | 59 | (8.7) | 109 | (8.8) | 96 | (6.1) | 205 | (7.3) |
| Grade 3 | 10 | (1.5) | 15 | (1.2) | 11 | (0.7) | 26 | (0.9) |
| Dehydration | 15 | (2.2) | 37 | (3.0) | 69 | (4.4) | 106 | (3.8) |
| Grade 1 | 3 | (0.4) | 12 | (1.0) | 17 | (1.1) | 29 | (1.0) |
| Grade 2 | 7 | (1.0) | 16 | (1.3) | 33 | (2.1) | 49 | (1.8) |
| Grade 3 | 5 | (0.7) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Diabetes mellitus | 3 | (0.4) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



C Confidential

# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Diabetes mellitus | 3 | (0.4) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diabetes mellitus inadequate control | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diabetic metabolic decompensation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrolyte imbalance | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Failure to thrive | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Fluid overload | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Fluid retention | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Glucose tolerance impaired | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gout | 0 | (0.0) | 1 | (0.1) | 13 | (0.8) | 14 | (0.5) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperalbuminaemia | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Hyperamylasaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypercalcaemia | 19 | (2.8) | 29 | (2.4) | 28 | (1.8) | 57 | (2.0) |
| Grade 1 | 10 | (1.5) | 15 | (1.2) | 20 | (1.3) | 35 | (1.3) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 6 | (0.9) | 8 | (0.6) | 2 | (0.1) | 10 | (0.4) |
| Grade 4 | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Hypercholesterolaemia | 9 | (1.3) | 13 | (1.1) | 12 | (0.8) | 25 | (0.9) |
| Grade 1 | 8 | (1.2) | 9 | (0.7) | 9 | (0.6) | 18 | (0.6) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperglycaemia | 28 | (4.1) | 64 | (5.2) | 66 | (4.2) | 130 | (4.6) |
| Grade 1 | 13 | (1.9) | 35 | (2.8) | 36 | (2.3) | 71 | (2.5) |
| Grade 2 | 5 | (0.7) | 17 | (1.4) | 13 | (0.8) | 30 | (1.1) |



C Confidential

# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hyperglycaemia | 28 | (4.1) | 64 | (5.2) | 66 | (4.2) | 130 | (4.6) |
| Grade 3 | 8 | (1.2) | 10 | (0.8) | 16 | (1.0) | 26 | (0.9) |
| Grade 4 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Hyperkalaemia | 10 | (1.5) | 23 | (1.9) | 38 | (2.4) | 61 | (2.2) |
| Grade 1 | 8 | (1.2) | 16 | (1.3) | 25 | (1.6) | 41 | (1.5) |
| Grade 2 | 2 | (0.3) | 7 | (0.6) | 9 | (0.6) | 16 | (0.6) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hyperlipidaemia | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypermagnesaemia | 1 | (0.1) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Hypernatraemia | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Hyperphagia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperphosphataemia | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Hypertriglyceridaemia | 17 | (2.5) | 25 | (2.0) | 55 | (3.5) | 80 | (2.9) |
| Grade 1 | 10 | (1.5) | 15 | (1.2) | 27 | (1.7) | 42 | (1.5) |
| Grade 2 | 3 | (0.4) | 5 | (0.4) | 17 | (1.1) | 22 | (0.8) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 11 | (0.7) | 14 | (0.5) |
| Grade 4 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hyperuricaemia | 5 | (0.7) | 8 | (0.6) | 30 | (1.9) | 38 | (1.4) |
| Grade 1 | 5 | (0.7) | 7 | (0.6) | 24 | (1.5) | 31 | (1.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Hypoalbuminaemia | 17 | (2.5) | 38 | (3.1) | 51 | (3.3) | 89 | (3.2) |
| Grade 1 | 8 | (1.2) | 20 | (1.6) | 17 | (1.1) | 37 | (1.3) |
| Grade 2 | 8 | (1.2) | 13 | (1.1) | 24 | (1.5) | 37 | (1.3) |
| Grade 3 | 1 | (0.1) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Hypocalcaemia | 12 | (1.8) | 20 | (1.6) | 30 | (1.9) | 50 | (1.8) |
| Grade 1 | 9 | (1.3) | 16 | (1.3) | 24 | (1.5) | 40 | (1.4) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypochloraemia | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypoglycaemia | 1 | (0.1) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hypoglycaemia | 1 | (0.1) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypokalaemia | 21 | (3.1) | 49 | (4.0) | 75 | (4.8) | 124 | (4.4) |
| Grade 1 | 10 | (1.5) | 29 | (2.4) | 53 | (3.4) | 82 | (2.9) |
| Grade 2 | 4 | (0.6) | 9 | (0.7) | 8 | (0.5) | 17 | (0.6) |
| Grade 3 | 7 | (1.0) | 11 | (0.9) | 11 | (0.7) | 22 | (0.8) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Hypomagnesaemia | 20 | (2.9) | 48 | (3.9) | 32 | (2.0) | 80 | (2.9) |
| Grade 1 | 19 | (2.8) | 42 | (3.4) | 28 | (1.8) | 70 | (2.5) |
| Grade 2 | 1 | (0.1) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Hyponatraemia | 27 | (4.0) | 58 | (4.7) | 88 | (5.6) | 146 | (5.2) |
| Grade 1 | 11 | (1.6) | 28 | (2.3) | 49 | (3.1) | 77 | (2.8) |
| Grade 2 | 3 | (0.4) | 6 | (0.5) | 1 | (0.1) | 7 | (0.3) |
| Grade 3 | 11 | (1.6) | 22 | (1.8) | 33 | (2.1) | 55 | (2.0) |
| Grade 4 | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Hypophagia | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Hypophosphataemia | 8 | (1.2) | 21 | (1.7) | 35 | (2.2) | 56 | (2.0) |
| Grade 1 | 3 | (0.4) | 11 | (0.9) | 13 | (0.8) | 24 | (0.9) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 14 | (0.9) | 18 | (0.6) |
| Grade 3 | 4 | (0.6) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypoproteinaemia | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hypovolaemia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Increased appetite | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Insulin resistant diabetes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iron deficiency | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lactic acidosis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lactose intolerance | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Malnutrition | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Malnutrition | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metabolic acidosis | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Metabolic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Obesity | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Polydipsia | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Tumour lysis syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Type 1 diabetes mellitus | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Type 2 diabetes mellitus | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vitamin B12 deficiency | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Vitamin D deficiency | 1 | (0.1) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| **Musculoskeletal and connective tissue disorders** | **295** | **(43.3)** | **531** | **(43.1)** | **881** | **(56.2)** | **1,412** | **(50.4)** |
| Grade 1 | 160 | (23.5) | 286 | (23.2) | 514 | (32.8) | 800 | (28.6) |
| Grade 2 | 103 | (15.1) | 189 | (15.3) | 297 | (19.0) | 486 | (17.4) |
| Grade 3 | 31 | (4.5) | 55 | (4.5) | 69 | (4.4) | 124 | (4.4) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Amyotrophy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ankylosing spondylitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Arthralgia | 75 | (11.0) | 167 | (13.6) | 337 | (21.5) | 504 | (18.0) |
| Grade 1 | 41 | (6.0) | 102 | (8.3) | 235 | (15.0) | 337 | (12.0) |
| Grade 2 | 27 | (4.0) | 54 | (4.4) | 96 | (6.1) | 150 | (5.4) |
| Grade 3 | 7 | (1.0) | 11 | (0.9) | 6 | (0.4) | 17 | (0.6) |
| Arthritis | 9 | (1.3) | 13 | (1.1) | 28 | (1.8) | 41 | (1.5) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Arthritis | 9 | (1.3) | 13 | (1.1) | 28 | (1.8) | 41 | (1.5) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 18 | (1.1) | 22 | (0.8) |
| Grade 2 | 6 | (0.9) | 8 | (0.6) | 10 | (0.6) | 18 | (0.6) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Arthropathy | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Axillary mass | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Back disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Back pain | 73 | (10.7) | 133 | (10.8) | 216 | (13.8) | 349 | (12.5) |
| Grade 1 | 44 | (6.5) | 73 | (5.9) | 124 | (7.9) | 197 | (7.0) |
| Grade 2 | 19 | (2.8) | 40 | (3.2) | 74 | (4.7) | 114 | (4.1) |
| Grade 3 | 10 | (1.5) | 20 | (1.6) | 18 | (1.1) | 38 | (1.4) |
| Bone lesion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bone pain | 12 | (1.8) | 24 | (1.9) | 29 | (1.9) | 53 | (1.9) |
| Grade 1 | 3 | (0.4) | 7 | (0.6) | 19 | (1.2) | 26 | (0.9) |
| Grade 2 | 5 | (0.7) | 10 | (0.8) | 9 | (0.6) | 19 | (0.7) |
| Grade 3 | 3 | (0.4) | 6 | (0.5) | 1 | (0.1) | 7 | (0.3) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bursa disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bursitis | 6 | (0.9) | 7 | (0.6) | 3 | (0.2) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 2 | 4 | (0.6) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Chondrocalcinosis pyrophosphate | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clubbing | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Coccydynia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Costochondritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dupuytren's contracture | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Exostosis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Fibromyalgia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fistula | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Fistula | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Flank pain | 5 | (0.7) | 13 | (1.1) | 37 | (2.4) | 50 | (1.8) |
| Grade 1 | 3 | (0.4) | 8 | (0.6) | 24 | (1.5) | 32 | (1.1) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Fracture pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Groin pain | 5 | (0.7) | 12 | (1.0) | 21 | (1.3) | 33 | (1.2) |
| Grade 1 | 4 | (0.6) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Growing pains | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hypercreatinaemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Inguinal mass | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Intervertebral disc protrusion | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Jaw disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Joint effusion | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Joint instability | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Joint range of motion decreased | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Joint stiffness | 2 | (0.3) | 6 | (0.5) | 12 | (0.8) | 18 | (0.6) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 9 | (0.6) | 14 | (0.5) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Joint swelling | 5 | (0.7) | 9 | (0.7) | 18 | (1.1) | 27 | (1.0) |
| Grade 1 | 5 | (0.7) | 8 | (0.6) | 14 | (0.9) | 22 | (0.8) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Kyphosis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Limb discomfort | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Lower extremity mass | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mastication disorder | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mobility decreased | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Muscle atrophy | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Muscle fatigue | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Muscle haemorrhage | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle necrosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle spasms | 16 | (2.3) | 31 | (2.5) | 52 | (3.3) | 83 | (3.0) |
| Grade 1 | 15 | (2.2) | 30 | (2.4) | 46 | (2.9) | 76 | (2.7) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Muscle tightness | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Muscle twitching | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscular weakness | 12 | (1.8) | 25 | (2.0) | 64 | (4.1) | 89 | (3.2) |
| Grade 1 | 7 | (1.0) | 14 | (1.1) | 38 | (2.4) | 52 | (1.9) |
| Grade 2 | 5 | (0.7) | 10 | (0.8) | 17 | (1.1) | 27 | (1.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Musculoskeletal chest pain | 21 | (3.1) | 51 | (4.1) | 56 | (3.6) | 107 | (3.8) |
| Grade 1 | 18 | (2.6) | 37 | (3.0) | 40 | (2.6) | 77 | (2.8) |
| Grade 2 | 2 | (0.3) | 8 | (0.6) | 14 | (0.9) | 22 | (0.8) |
| Grade 3 | 1 | (0.1) | 6 | (0.5) | 2 | (0.1) | 8 | (0.3) |
| Musculoskeletal discomfort | 8 | (1.2) | 11 | (0.9) | 11 | (0.7) | 22 | (0.8) |
| Grade 1 | 8 | (1.2) | 11 | (0.9) | 11 | (0.7) | 22 | (0.8) |
| Musculoskeletal pain | 65 | (9.5) | 105 | (8.5) | 121 | (7.7) | 226 | (8.1) |
| Grade 1 | 35 | (5.1) | 57 | (4.6) | 85 | (5.4) | 142 | (5.1) |
| Grade 2 | 24 | (3.5) | 40 | (3.2) | 28 | (1.8) | 68 | (2.4) |
| Grade 3 | 6 | (0.9) | 8 | (0.6) | 8 | (0.5) | 16 | (0.6) |
| Musculoskeletal stiffness | 3 | (0.4) | 9 | (0.7) | 30 | (1.9) | 39 | (1.4) |
| Grade 1 | 2 | (0.3) | 8 | (0.6) | 29 | (1.9) | 37 | (1.3) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Musculoskeletal stiffness | 3 | (0.4) | 9 | (0.7) | 30 | (1.9) | 39 | (1.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myalgia | 35 | (5.1) | 73 | (5.9) | 180 | (11.5) | 253 | (9.0) |
| Grade 1 | 25 | (3.7) | 57 | (4.6) | 143 | (9.1) | 200 | (7.1) |
| Grade 2 | 9 | (1.3) | 15 | (1.2) | 30 | (1.9) | 45 | (1.6) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Myalgia intercostal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myopathy | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myositis | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Neck mass | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Neck pain | 22 | (3.2) | 39 | (3.2) | 55 | (3.5) | 94 | (3.4) |
| Grade 1 | 17 | (2.5) | 28 | (2.3) | 45 | (2.9) | 73 | (2.6) |
| Grade 2 | 4 | (0.6) | 9 | (0.7) | 9 | (0.6) | 18 | (0.6) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Nodal osteoarthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Osteitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Osteoarthritis | 3 | (0.4) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Osteolysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Osteonecrosis of jaw | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Osteopenia | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Osteoporosis | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Osteoporotic fracture | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Osteosclerosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pain in extremity | 42 | (6.2) | 69 | (5.6) | 168 | (10.7) | 237 | (8.5) |
| Grade 1 | 30 | (4.4) | 48 | (3.9) | 118 | (7.5) | 166 | (5.9) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pain in extremity | 42 | (6.2) | 69 | (5.6) | 168 | (10.7) | 237 | (8.5) |
| Grade 2 | 8 | (1.2) | 16 | (1.3) | 43 | (2.7) | 59 | (2.1) |
| Grade 3 | 4 | (0.6) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Pain in jaw | 4 | (0.6) | 8 | (0.6) | 17 | (1.1) | 25 | (0.9) |
| Grade 1 | 4 | (0.6) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Pathological fracture | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Periarthritis | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Plantar fasciitis | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Polyarthritis | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Polymyalgia rheumatica | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Rhabdomyolysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rheumatic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rheumatoid arthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rotator cuff syndrome | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sjogren's syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Spinal column stenosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Spinal osteoarthritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Spinal pain | 3 | (0.4) | 8 | (0.6) | 7 | (0.4) | 15 | (0.5) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Spondylitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



C Confidential

## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Spondylitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Spondylolisthesis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Synovial cyst | 3 | (0.4) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Synovitis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Temporomandibular joint syndrome | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Tendon disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tendon pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tendonitis | 1 | (0.1) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Tenosynovitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Torticollis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Trigger finger | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Trismus | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper extremity mass | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **36** | **(5.3)** | **68** | **(5.5)** | **190** | **(12.1)** | **258** | **(9.2)** |
| Grade 1 | 9 | (1.3) | 17 | (1.4) | 86 | (5.5) | 103 | (3.7) |
| Grade 2 | 10 | (1.5) | 23 | (1.9) | 53 | (3.4) | 76 | (2.7) |
| Grade 3 | 16 | (2.3) | 26 | (2.1) | 44 | (2.8) | 70 | (2.5) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Abdominal neoplasm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Acrochordon | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Adenocarcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Adenocarcinoma gastric | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Basal cell carcinoma | 1 | (0.1) | 3 | (0.2) | 18 | (1.1) | 21 | (0.8) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Basosquamous carcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Benign lung neoplasm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bowen's disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breast cancer | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cancer pain | 8 | (1.2) | 11 | (0.9) | 11 | (0.7) | 22 | (0.8) |
| Grade 1 | 4 | (0.6) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 2 | 2 | (0.3) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Cerebral haemangioma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Colon cancer metastatic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Desmoplastic melanoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ear neoplasm malignant | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastric cancer | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal carcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemangioma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemangioma of skin | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infected neoplasm | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Intracranial tumour haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Intracranial tumour haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Invasive ductal breast carcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratoacanthoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Leiomyosarcoma | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lipoma | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Lung neoplasm malignant | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lymphangiosis carcinomatosa | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malignant melanoma | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Malignant melanoma in situ | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malignant neoplasm progression | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Malignant pleural effusion | 3 | (0.4) | 6 | (0.5) | 0 | (0.0) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Melanocytic naevus | 0 | (0.0) | 0 | (0.0) | 12 | (0.8) | 12 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 11 | (0.7) | 11 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastases to bone | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Metastases to central nervous system | 3 | (0.4) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastases to large intestine | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastases to lymph nodes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Metastases to meninges | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastases to muscle | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastatic malignant melanoma | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastatic pain | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Neoplasm malignant | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Neoplasm skin | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Neoplasm swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oncologic complication | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Papillary thyroid cancer | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Papilloma | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Paraneoplastic syndrome | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pericardial effusion malignant | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Prostate cancer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rectal cancer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seborrhoeic keratosis | 1 | (0.1) | 2 | (0.2) | 16 | (1.0) | 18 | (0.6) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 15 | (1.0) | 17 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin neoplasm bleeding | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin papilloma | 1 | (0.1) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Squamous cell carcinoma | 0 | (0.0) | 1 | (0.1) | 19 | (1.2) | 20 | (0.7) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Squamous cell carcinoma | 0 | (0.0) | 1 | (0.1) | 19 | (1.2) | 20 | (0.7) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Squamous cell carcinoma of skin | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Thyroid neoplasm | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Tumour associated fever | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tumour exudation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tumour haemorrhage | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tumour necrosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Tumour pain | 10 | (1.5) | 22 | (1.8) | 38 | (2.4) | 60 | (2.1) |
| Grade 1 | 3 | (0.4) | 6 | (0.5) | 16 | (1.0) | 22 | (0.8) |
| Grade 2 | 2 | (0.3) | 6 | (0.5) | 15 | (1.0) | 21 | (0.8) |
| Grade 3 | 5 | (0.7) | 10 | (0.8) | 7 | (0.4) | 17 | (0.6) |
| Vulval cancer metastatic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Nervous system disorders** | **207** | **(30.4)** | **386** | **(31.3)** | **651** | **(41.5)** | **1,037** | **(37.0)** |
| Grade 1 | 123 | (18.0) | 248 | (20.1) | 442 | (28.2) | 690 | (24.7) |
| Grade 2 | 61 | (8.9) | 104 | (8.4) | 135 | (8.6) | 239 | (8.5) |
| Grade 3 | 18 | (2.6) | 28 | (2.3) | 63 | (4.0) | 91 | (3.3) |
| Grade 4 | 2 | (0.3) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 5 | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Action tremor | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ageusia | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Akathisia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Altered state of consciousness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Amnesia | 2 | (0.3) | 6 | (0.5) | 10 | (0.6) | 16 | (0.6) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 9 | (0.6) | 14 | (0.5) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Amnesia | 2 | (0.3) | 6 | (0.5) | 10 | (0.6) | 16 | (0.6) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Amnestic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Anosmia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Aphasia | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Aphonia | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Apraxia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Ataxia | 1 | (0.1) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Axonal neuropathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Balance disorder | 3 | (0.4) | 5 | (0.4) | 18 | (1.1) | 23 | (0.8) |
| Grade 1 | 3 | (0.4) | 5 | (0.4) | 14 | (0.9) | 19 | (0.7) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Brain oedema | 1 | (0.1) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Burning sensation | 1 | (0.1) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Carpal tunnel syndrome | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cerebellar syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cerebral haematoma | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cerebral haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



C Confidential

# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Cerebral haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cerebral infarction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cerebral ischaemia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cerebrovascular accident | 2 | (0.3) | 6 | (0.5) | 6 | (0.4) | 12 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cervical radiculopathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cognitive disorder | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Coordination abnormal | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Depressed level of consciousness | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Developmental coordination disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Disturbance in attention | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Dizziness | 48 | (7.0) | 94 | (7.6) | 150 | (9.6) | 244 | (8.7) |
| Grade 1 | 39 | (5.7) | 83 | (6.7) | 128 | (8.2) | 211 | (7.5) |
| Grade 2 | 8 | (1.2) | 10 | (0.8) | 16 | (1.0) | 26 | (0.9) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Dizziness postural | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Dysaesthesia | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Dysarthria | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Dysgeusia | 14 | (2.1) | 24 | (1.9) | 45 | (2.9) | 69 | (2.5) |
| Grade 1 | 12 | (1.8) | 21 | (1.7) | 37 | (2.4) | 58 | (2.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Dysgeusia | 14 | (2.1) | 24 | (1.9) | 45 | (2.9) | 69 | (2.5) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Dyskinesia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Embolic stroke | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Encephalopathy | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Epilepsy | 2 | (0.3) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Extensor plantar response | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Facial nerve disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Facial neuralgia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Facial paresis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Guillain-Barre syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhage intracranial | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhagic stroke | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Head discomfort | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Headache | 64 | (9.4) | 122 | (9.9) | 278 | (17.7) | 400 | (14.3) |
| Grade 1 | 45 | (6.6) | 89 | (7.2) | 225 | (14.4) | 314 | (11.2) |
| Grade 2 | 16 | (2.3) | 30 | (2.4) | 43 | (2.7) | 73 | (2.6) |
| Grade 3 | 3 | (0.4) | 3 | (0.2) | 10 | (0.6) | 13 | (0.5) |
| Hemiparesis | 2 | (0.3) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hemiplegia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Horner's syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



C Confidential

# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hydrocephalus | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperaesthesia | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Hypersomnia | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hypoaesthesia | 18 | (2.6) | 24 | (1.9) | 37 | (2.4) | 61 | (2.2) |
| Grade 1 | 18 | (2.6) | 23 | (1.9) | 34 | (2.2) | 57 | (2.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Hypogeusia | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypotonia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Incoherent | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intracranial aneurysm | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Ischaemic stroke | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Judgement impaired | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lacunar infarction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lethargy | 5 | (0.7) | 15 | (1.2) | 18 | (1.1) | 33 | (1.2) |
| Grade 1 | 4 | (0.6) | 11 | (0.9) | 16 | (1.0) | 27 | (1.0) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Loss of consciousness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lumbar radiculopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Memory impairment | 0 | (0.0) | 2 | (0.2) | 21 | (1.3) | 23 | (0.8) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 19 | (1.2) | 21 | (0.8) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Meningitis noninfective | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Migraine | 1 | (0.1) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |



C Confidential

# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Migraine | 1 | (0.1) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Migraine with aura | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Monoparesis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle contractions involuntary | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle spasticity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Myasthenic syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myelitis transverse | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Myoclonus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Nerve compression | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nerve root compression | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nervous system disorder | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neuralgia | 0 | (0.0) | 3 | (0.2) | 13 | (0.8) | 16 | (0.6) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Neurological decompensation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neuropathy peripheral | 14 | (2.1) | 30 | (2.4) | 46 | (2.9) | 76 | (2.7) |
| Grade 1 | 11 | (1.6) | 23 | (1.9) | 36 | (2.3) | 59 | (2.1) |
| Grade 2 | 3 | (0.4) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Neurotoxicity | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Normal pressure hydrocephalus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nystagmus | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Optic neuritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Paraesthesia | 15 | (2.2) | 28 | (2.3) | 59 | (3.8) | 87 | (3.1) |
| Grade 1 | 10 | (1.5) | 20 | (1.6) | 53 | (3.4) | 73 | (2.6) |
| Grade 2 | 4 | (0.6) | 7 | (0.6) | 5 | (0.3) | 12 | (0.4) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Paralysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Parosmia | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Partial seizures | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Peripheral motor neuropathy | 3 | (0.4) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral sensory neuropathy | 11 | (1.6) | 14 | (1.1) | 15 | (1.0) | 29 | (1.0) |
| Grade 1 | 7 | (1.0) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Grade 2 | 4 | (0.6) | 7 | (0.6) | 2 | (0.1) | 9 | (0.3) |
| Peroneal nerve palsy | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Phantom pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Polyneuropathy | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Poor quality sleep | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Post herpetic neuralgia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Presyncope | 0 | (0.0) | 2 | (0.2) | 15 | (1.0) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Psychomotor hyperactivity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Radial nerve palsy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Radiculopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Restless legs syndrome | 2 | (0.3) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sciatica | 3 | (0.4) | 9 | (0.7) | 22 | (1.4) | 31 | (1.1) |
| Grade 1 | 1 | (0.1) | 6 | (0.5) | 12 | (0.8) | 18 | (0.6) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seizure | 1 | (0.1) | 4 | (0.3) | 22 | (1.4) | 26 | (0.9) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 10 | (0.6) | 12 | (0.4) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Sensory disturbance | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sensory loss | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sinus headache | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Slow speech | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Somnolence | 5 | (0.7) | 9 | (0.7) | 13 | (0.8) | 22 | (0.8) |
| Grade 1 | 3 | (0.4) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Spinal cord compression | 2 | (0.3) | 3 | (0.2) | 10 | (0.6) | 13 | (0.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Syncope | 9 | (1.3) | 13 | (1.1) | 20 | (1.3) | 33 | (1.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 10 | (0.6) | 12 | (0.4) |
| Grade 2 | 4 | (0.6) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 3 | 4 | (0.6) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Tension headache | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Toxic leukoencephalopathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Toxic neuropathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Transient ischaemic attack | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Tremor | 3 | (0.4) | 4 | (0.3) | 21 | (1.3) | 25 | (0.9) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 19 | (1.2) | 23 | (0.8) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Trigeminal neuralgia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| VIIth nerve paralysis | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vasogenic cerebral oedema | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Visual field defect | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Vocal cord paralysis | 1 | (0.1) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Psychiatric disorders** | **106** | **(15.5)** | **208** | **(16.9)** | **315** | **(20.1)** | **523** | **(18.7)** |
| Grade 1 | 59 | (8.7) | 125 | (10.1) | 219 | (14.0) | 344 | (12.3) |
| Grade 2 | 36 | (5.3) | 69 | (5.6) | 83 | (5.3) | 152 | (5.4) |
| Grade 3 | 9 | (1.3) | 12 | (1.0) | 10 | (0.6) | 22 | (0.8) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Abnormal dreams | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Adjustment disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Adjustment disorder with depressed mood | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Affect lability | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Affective disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Aggression | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Agitation | 4 | (0.6) | 5 | (0.4) | 12 | (0.8) | 17 | (0.6) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Anhedonia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Anxiety | 32 | (4.7) | 60 | (4.9) | 81 | (5.2) | 141 | (5.0) |
| Grade 1 | 13 | (1.9) | 27 | (2.2) | 53 | (3.4) | 80 | (2.9) |
| Grade 2 | 16 | (2.3) | 29 | (2.4) | 27 | (1.7) | 56 | (2.0) |
| Grade 3 | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Anxiety disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Apathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Binge eating | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bradyphrenia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Bulimia nervosa | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Claustrophobia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Completed suicide | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Confusional state | 8 | (1.2) | 21 | (1.7) | 37 | (2.4) | 58 | (2.1) |
| Grade 1 | 2 | (0.3) | 7 | (0.6) | 22 | (1.4) | 29 | (1.0) |
| Grade 2 | 3 | (0.4) | 10 | (0.8) | 9 | (0.6) | 19 | (0.7) |
| Grade 3 | 3 | (0.4) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Delirium | 5 | (0.7) | 9 | (0.7) | 2 | (0.1) | 11 | (0.4) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 5 | (0.7) | 8 | (0.6) | 1 | (0.1) | 9 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Depressed mood | 3 | (0.4) | 6 | (0.5) | 2 | (0.1) | 8 | (0.3) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Depression | 23 | (3.4) | 42 | (3.4) | 61 | (3.9) | 103 | (3.7) |
| Grade 1 | 14 | (2.1) | 29 | (2.4) | 42 | (2.7) | 71 | (2.5) |
| Grade 2 | 9 | (1.3) | 13 | (1.1) | 18 | (1.1) | 31 | (1.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Disorientation | 3 | (0.4) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dysphoria | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Food aversion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hallucination | 2 | (0.3) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |



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## Subjects With Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hallucination | 2 | (0.3) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hallucination, auditory | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hallucination, visual | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Insomnia | 42 | (6.2) | 85 | (6.9) | 133 | (8.5) | 218 | (7.8) |
| Grade 1 | 34 | (5.0) | 70 | (5.7) | 103 | (6.6) | 173 | (6.2) |
| Grade 2 | 8 | (1.2) | 14 | (1.1) | 29 | (1.9) | 43 | (1.5) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Irritability | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Libido decreased | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mental disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mental status changes | 6 | (0.9) | 7 | (0.6) | 5 | (0.3) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Middle insomnia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mood altered | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Mood swings | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Nervousness | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nightmare | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Panic attack | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Personality change | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Personality change | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Phobia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Psychomotor retardation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Psychosomatic disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Psychotic disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Restlessness | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sleep disorder | 2 | (0.3) | 2 | (0.2) | 11 | (0.7) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Stress | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Substance-induced psychotic disorder | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Suicidal ideation | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Tension | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Trance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Renal and urinary disorders** | **52** | **(7.6)** | **99** | **(8.0)** | **172** | **(11.0)** | **271** | **(9.7)** |
| Grade 1 | 29 | (4.3) | 56 | (4.5) | 109 | (7.0) | 165 | (5.9) |
| Grade 2 | 13 | (1.9) | 25 | (2.0) | 43 | (2.7) | 68 | (2.4) |
| Grade 3 | 9 | (1.3) | 15 | (1.2) | 17 | (1.1) | 32 | (1.1) |
| Grade 4 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Acute kidney injury | 7 | (1.0) | 13 | (1.1) | 27 | (1.7) | 40 | (1.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 11 | (0.7) | 14 | (0.5) |
| Grade 2 | 0 | (0.0) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 3 | 4 | (0.6) | 6 | (0.5) | 8 | (0.5) | 14 | (0.5) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Azotaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Azotaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bladder spasm | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Calculus ureteric | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chromaturia | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chronic kidney disease | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cystitis noninfective | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dysuria | 11 | (1.6) | 20 | (1.6) | 26 | (1.7) | 46 | (1.6) |
| Grade 1 | 8 | (1.2) | 15 | (1.2) | 23 | (1.5) | 38 | (1.4) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haematuria | 7 | (1.0) | 13 | (1.1) | 26 | (1.7) | 39 | (1.4) |
| Grade 1 | 5 | (0.7) | 10 | (0.8) | 26 | (1.7) | 36 | (1.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haemoglobinuria | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hydronephrosis | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Hypertonic bladder | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Incontinence | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Microalbuminuria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Micturition disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Micturition urgency | 2 | (0.3) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Nephrolithiasis | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Nocturia | 3 | (0.4) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 1 | 3 | (0.4) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Obstructive uropathy | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pelvi-ureteric obstruction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumaturia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pollakiuria | 8 | (1.2) | 12 | (1.0) | 34 | (2.2) | 46 | (1.6) |
| Grade 1 | 7 | (1.0) | 11 | (0.9) | 24 | (1.5) | 35 | (1.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Polyuria | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Postrenal failure | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Proteinuria | 6 | (0.9) | 9 | (0.7) | 5 | (0.3) | 14 | (0.5) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 4 | (0.6) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Pyelocaliectasis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Renal colic | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Renal cyst | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Renal failure | 5 | (0.7) | 8 | (0.6) | 17 | (1.1) | 25 | (0.9) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 4 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Renal impairment | 3 | (0.4) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Renal infarct | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Renal pain | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tubulointerstitial nephritis | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urge incontinence | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Urge incontinence | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary bladder polyp | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary hesitation | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Urinary incontinence | 0 | (0.0) | 2 | (0.2) | 13 | (0.8) | 15 | (0.5) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 11 | (0.7) | 12 | (0.4) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Urinary retention | 1 | (0.1) | 6 | (0.5) | 8 | (0.5) | 14 | (0.5) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary tract disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urinary tract obstruction | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary tract pain | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urine flow decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urine odour abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Reproductive system and breast disorders** | **19** | **(2.8)** | **31** | **(2.5)** | **98** | **(6.3)** | **129** | **(4.6)** |
| Grade 1 | 14 | (2.1) | 22 | (1.8) | 72 | (4.6) | 94 | (3.4) |
| Grade 2 | 4 | (0.6) | 8 | (0.6) | 23 | (1.5) | 31 | (1.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Amenorrhoea | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Atrophic vulvovaginitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Balanoposthitis | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Benign prostatic hyperplasia | 0 | (0.0) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Breast cyst | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breast haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Breast haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breast oedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Breast pain | 1 | (0.1) | 2 | (0.2) | 10 | (0.6) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 8 | (0.5) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Breast swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breast tenderness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cervix oedema | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dysfunctional uterine bleeding | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dysmenorrhoea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erectile dysfunction | 2 | (0.3) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Genital discomfort | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Genital haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Genital rash | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gynaecomastia | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Haematospermia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Menopausal symptoms | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Menorrhagia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Menstrual disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Menstruation irregular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metrorrhagia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Nipple pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Nipple swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oedema genital | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pelvic pain | 2 | (0.3) | 5 | (0.4) | 18 | (1.1) | 23 | (0.8) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 11 | (0.7) | 14 | (0.5) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Penile erythema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Prostatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pruritus genital | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Scrotal erythema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Scrotal oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Scrotal pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sexual dysfunction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Testicular atrophy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Testicular pain | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Testicular swelling | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vaginal discharge | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Vaginal haemorrhage | 4 | (0.6) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 4 | (0.6) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulval disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Vulvar erosion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal burning sensation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Vulvovaginal discomfort | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal dryness | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Vulvovaginal pain | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal pruritus | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Respiratory, thoracic and mediastinal disorders** | **350** | **(51.3)** | **671** | **(54.5)** | **720** | **(45.9)** | **1,391** | **(49.7)** |
| Grade 1 | 147 | (21.6) | 266 | (21.6) | 456 | (29.1) | 722 | (25.8) |
| Grade 2 | 120 | (17.6) | 247 | (20.0) | 178 | (11.4) | 425 | (15.2) |
| Grade 3 | 57 | (8.4) | 107 | (8.7) | 72 | (4.6) | 179 | (6.4) |
| Grade 4 | 14 | (2.1) | 30 | (2.4) | 9 | (0.6) | 39 | (1.4) |
| Grade 5 | 12 | (1.8) | 21 | (1.7) | 5 | (0.3) | 26 | (0.9) |
| Acute respiratory failure | 2 | (0.3) | 7 | (0.6) | 3 | (0.2) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Allergic cough | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Allergic respiratory disease | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Allergic sinusitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Asthma | 3 | (0.4) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 3 | (0.4) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Atelectasis | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bronchial hyperreactivity | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Bronchial obstruction | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Bronchial obstruction | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchiectasis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Bronchitis chronic | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchospasm | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bronchostenosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Catarrh | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Choking sensation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chronic obstructive pulmonary disease | 15 | (2.2) | 23 | (1.9) | 7 | (0.4) | 30 | (1.1) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 2 | 4 | (0.6) | 7 | (0.6) | 5 | (0.3) | 12 | (0.4) |
| Grade 3 | 8 | (1.2) | 11 | (0.9) | 1 | (0.1) | 12 | (0.4) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Chronic respiratory failure | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cough | 130 | (19.1) | 256 | (20.8) | 359 | (22.9) | 615 | (22.0) |
| Grade 1 | 85 | (12.5) | 163 | (13.2) | 306 | (19.5) | 469 | (16.8) |
| Grade 2 | 41 | (6.0) | 89 | (7.2) | 51 | (3.3) | 140 | (5.0) |
| Grade 3 | 4 | (0.6) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Diaphragmatic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diffuse alveolar damage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diffuse panbronchiolitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dry throat | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dysaesthesia pharynx | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dysphonia | 21 | (3.1) | 40 | (3.2) | 28 | (1.8) | 68 | (2.4) |
| Grade 1 | 18 | (2.6) | 34 | (2.8) | 25 | (1.6) | 59 | (2.1) |
| Grade 2 | 3 | (0.4) | 6 | (0.5) | 1 | (0.1) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dyspnoea | 156 | (22.9) | 286 | (23.2) | 248 | (15.8) | 534 | (19.1) |
| Grade 1 | 73 | (10.7) | 121 | (9.8) | 156 | (10.0) | 277 | (9.9) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Dyspnoea | 156 | (22.9) | 286 | (23.2) | 248 | (15.8) | 534 | (19.1) |
| Grade 2 | 58 | (8.5) | 117 | (9.5) | 62 | (4.0) | 179 | (6.4) |
| Grade 3 | 23 | (3.4) | 46 | (3.7) | 25 | (1.6) | 71 | (2.5) |
| Grade 4 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dyspnoea at rest | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dyspnoea exertional | 10 | (1.5) | 36 | (2.9) | 44 | (2.8) | 80 | (2.9) |
| Grade 1 | 8 | (1.2) | 23 | (1.9) | 32 | (2.0) | 55 | (2.0) |
| Grade 2 | 1 | (0.1) | 12 | (1.0) | 10 | (0.6) | 22 | (0.8) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Epistaxis | 13 | (1.9) | 17 | (1.4) | 32 | (2.0) | 49 | (1.8) |
| Grade 1 | 11 | (1.6) | 15 | (1.2) | 27 | (1.7) | 42 | (1.5) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Haemoptysis | 49 | (7.2) | 87 | (7.1) | 20 | (1.3) | 107 | (3.8) |
| Grade 1 | 36 | (5.3) | 68 | (5.5) | 14 | (0.9) | 82 | (2.9) |
| Grade 2 | 9 | (1.3) | 14 | (1.1) | 2 | (0.1) | 16 | (0.6) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haemothorax | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hiccups | 2 | (0.3) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypercapnia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperventilation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypoxia | 12 | (1.8) | 23 | (1.9) | 13 | (0.8) | 36 | (1.3) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 5 | (0.7) | 13 | (1.1) | 6 | (0.4) | 19 | (0.7) |
| Grade 3 | 5 | (0.7) | 8 | (0.6) | 3 | (0.2) | 11 | (0.4) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Increased bronchial secretion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Increased upper airway secretion | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Increased viscosity of nasal secretion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Interstitial lung disease | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Laryngeal discomfort | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Laryngeal haemorrhage | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Laryngeal inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Laryngeal pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lower respiratory tract congestion | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Lung consolidation | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lung disorder | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Lung infiltration | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nasal congestion | 6 | (0.9) | 22 | (1.8) | 61 | (3.9) | 83 | (3.0) |
| Grade 1 | 5 | (0.7) | 19 | (1.5) | 49 | (3.1) | 68 | (2.4) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 12 | (0.8) | 15 | (0.5) |
| Nasal discomfort | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nasal disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasal dryness | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nasal inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasal mucosal disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasal obstruction | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Nasal ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Obstructive airways disorder | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Oesophagobronchial fistula | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Oropharyngeal discomfort | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Oropharyngeal pain | 17 | (2.5) | 27 | (2.2) | 63 | (4.0) | 90 | (3.2) |
| Grade 1 | 15 | (2.2) | 24 | (1.9) | 61 | (3.9) | 85 | (3.0) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Orthopnoea | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Painful respiration | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Paranasal sinus discomfort | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Paranasal sinus hypersecretion | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pharyngeal erythema | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pharyngeal inflammation | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pharyngeal oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pleural effusion | 25 | (3.7) | 72 | (5.8) | 35 | (2.2) | 107 | (3.8) |
| Grade 1 | 2 | (0.3) | 9 | (0.7) | 8 | (0.5) | 17 | (0.6) |
| Grade 2 | 13 | (1.9) | 40 | (3.2) | 13 | (0.8) | 53 | (1.9) |
| Grade 3 | 10 | (1.5) | 20 | (1.6) | 14 | (0.9) | 34 | (1.2) |
| Grade 4 | 0 | (0.0) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Pleurisy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pleuritic pain | 5 | (0.7) | 10 | (0.8) | 10 | (0.6) | 20 | (0.7) |
| Grade 1 | 3 | (0.4) | 7 | (0.6) | 7 | (0.4) | 14 | (0.5) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumonia aspiration | 4 | (0.6) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pneumonia aspiration | 4 | (0.6) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 5 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pneumonitis | 28 | (4.1) | 50 | (4.1) | 37 | (2.4) | 87 | (3.1) |
| Grade 1 | 4 | (0.6) | 8 | (0.6) | 11 | (0.7) | 19 | (0.7) |
| Grade 2 | 10 | (1.5) | 18 | (1.5) | 16 | (1.0) | 34 | (1.2) |
| Grade 3 | 7 | (1.0) | 14 | (1.1) | 10 | (0.6) | 24 | (0.9) |
| Grade 4 | 4 | (0.6) | 7 | (0.6) | 0 | (0.0) | 7 | (0.3) |
| Grade 5 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Pneumothorax | 1 | (0.1) | 10 | (0.8) | 6 | (0.4) | 16 | (0.6) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumothorax spontaneous | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Productive cough | 43 | (6.3) | 81 | (6.6) | 61 | (3.9) | 142 | (5.1) |
| Grade 1 | 28 | (4.1) | 48 | (3.9) | 52 | (3.3) | 100 | (3.6) |
| Grade 2 | 13 | (1.9) | 31 | (2.5) | 9 | (0.6) | 40 | (1.4) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pulmonary congestion | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pulmonary embolism | 20 | (2.9) | 36 | (2.9) | 25 | (1.6) | 61 | (2.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 5 | (0.4) | 9 | (0.6) | 14 | (0.5) |
| Grade 3 | 13 | (1.9) | 21 | (1.7) | 12 | (0.8) | 33 | (1.2) |
| Grade 4 | 4 | (0.6) | 8 | (0.6) | 2 | (0.1) | 10 | (0.4) |
| Grade 5 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Pulmonary haemorrhage | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pulmonary hypertension | 2 | (0.3) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pulmonary infarction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pulmonary oedema | 2 | (0.3) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pulmonary pain | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pulmonary thrombosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pulmonary vascular disorder | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pulmonary venous thrombosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rales | 2 | (0.3) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Respiration abnormal | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory acidosis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Respiratory disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Respiratory distress | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory failure | 5 | (0.7) | 15 | (1.2) | 4 | (0.3) | 19 | (0.7) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Grade 5 | 2 | (0.3) | 6 | (0.5) | 0 | (0.0) | 6 | (0.2) |
| Respiratory tract congestion | 1 | (0.1) | 7 | (0.6) | 9 | (0.6) | 16 | (0.6) |
| Grade 1 | 1 | (0.1) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Respiratory tract haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rhinitis allergic | 5 | (0.7) | 13 | (1.1) | 21 | (1.3) | 34 | (1.2) |
| Grade 1 | 3 | (0.4) | 8 | (0.6) | 14 | (0.9) | 22 | (0.8) |
| Grade 2 | 2 | (0.3) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Rhinorrhoea | 16 | (2.3) | 23 | (1.9) | 30 | (1.9) | 53 | (1.9) |
| Grade 1 | 13 | (1.9) | 20 | (1.6) | 26 | (1.7) | 46 | (1.6) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Sinus congestion | 1 | (0.1) | 3 | (0.2) | 24 | (1.5) | 27 | (1.0) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 22 | (1.4) | 25 | (0.9) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Sinus disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Sleep apnoea syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sneezing | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Sputum discoloured | 3 | (0.4) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sputum increased | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Stridor | 4 | (0.6) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tachypnoea | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Throat irritation | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Throat tightness | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tonsillar disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tracheal inflammation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper respiratory tract congestion | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper respiratory tract inflammation | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Upper-airway cough syndrome | 3 | (0.4) | 8 | (0.6) | 21 | (1.3) | 29 | (1.0) |
| Grade 1 | 3 | (0.4) | 8 | (0.6) | 17 | (1.1) | 25 | (0.9) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Vocal cord cyst | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Wheezing | 14 | (2.1) | 27 | (2.2) | 25 | (1.6) | 52 | (1.9) |
| Grade 1 | 10 | (1.5) | 20 | (1.6) | 20 | (1.3) | 40 | (1.4) |
| Grade 2 | 3 | (0.4) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| **Skin and subcutaneous tissue disorders** | **222** | **(32.6)** | **419** | **(34.0)** | **941** | **(60.1)** | **1,360** | **(48.6)** |
| Grade 1 | 154 | (22.6) | 308 | (25.0) | 723 | (46.1) | 1,031 | (36.8) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **222** | **(32.6)** | **419** | **(34.0)** | **941** | **(60.1)** | **1,360** | **(48.6)** |
| Grade 2 | 61 | (8.9) | 97 | (7.9) | 192 | (12.3) | 289 | (10.3) |
| Grade 3 | 7 | (1.0) | 14 | (1.1) | 26 | (1.7) | 40 | (1.4) |
| Acantholysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Acne | 2 | (0.3) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Actinic keratosis | 1 | (0.1) | 2 | (0.2) | 18 | (1.1) | 20 | (0.7) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 16 | (1.0) | 18 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Alopecia | 9 | (1.3) | 18 | (1.5) | 34 | (2.2) | 52 | (1.9) |
| Grade 1 | 9 | (1.3) | 18 | (1.5) | 33 | (2.1) | 51 | (1.8) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Angioedema | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Anhidrosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blister | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Blood blister | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cold sweat | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dandruff | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Decubitus ulcer | 3 | (0.4) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Dermal cyst | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dermatitis | 2 | (0.3) | 6 | (0.5) | 14 | (0.9) | 20 | (0.7) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dermatitis acneiform | 3 | (0.4) | 16 | (1.3) | 16 | (1.0) | 32 | (1.1) |
| Grade 1 | 2 | (0.3) | 14 | (1.1) | 13 | (0.8) | 27 | (1.0) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Dermatitis allergic | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Dermatitis atopic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatitis bullous | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dermatitis contact | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatitis exfoliative | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatitis psoriasiform | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diffuse alopecia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Drug eruption | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dry skin | 28 | (4.1) | 66 | (5.4) | 99 | (6.3) | 165 | (5.9) |
| Grade 1 | 27 | (4.0) | 63 | (5.1) | 89 | (5.7) | 152 | (5.4) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 10 | (0.6) | 13 | (0.5) |
| Dyshidrotic eczema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ecchymosis | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Eczema | 8 | (1.2) | 9 | (0.7) | 33 | (2.1) | 42 | (1.5) |
| Grade 1 | 7 | (1.0) | 8 | (0.6) | 29 | (1.9) | 37 | (1.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Eczema asteatotic | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eczema nummular | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erythema | 10 | (1.5) | 21 | (1.7) | 71 | (4.5) | 92 | (3.3) |
| Grade 1 | 10 | (1.5) | 20 | (1.6) | 64 | (4.1) | 84 | (3.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Erythema multiforme | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Erythema nodosum | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Excessive granulation tissue | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Exfoliative rash | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Generalised erythema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Granuloma annulare | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Granuloma skin | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhage subcutaneous | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hair colour changes | 0 | (0.0) | 0 | (0.0) | 20 | (1.3) | 20 | (0.7) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 19 | (1.2) | 19 | (0.7) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hair disorder | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hair growth abnormal | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Hair texture abnormal | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hyperhidrosis | 7 | (1.0) | 15 | (1.2) | 41 | (2.6) | 56 | (2.0) |
| Grade 1 | 6 | (0.9) | 14 | (1.1) | 34 | (2.2) | 48 | (1.7) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Hyperkeratosis | 2 | (0.3) | 4 | (0.3) | 13 | (0.8) | 17 | (0.6) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 13 | (0.8) | 15 | (0.5) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypertrichosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ichthyosis acquired | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ingrowing nail | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intertrigo | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Intertrigo | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratosis pilaris | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Leukoplakia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lichen planus | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lichen sclerosus | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Lichenification | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lichenoid keratosis | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Linear IgA disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Macule | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Madarosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Melanocytic hyperplasia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Miliaria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mucocutaneous rash | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail discolouration | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nail disorder | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Nail dystrophy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail growth abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail ridging | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail toxicity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neurodermatitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Neutrophilic dermatosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Night sweats | 10 | (1.5) | 18 | (1.5) | 69 | (4.4) | 87 | (3.1) |
| Grade 1 | 8 | (1.2) | 15 | (1.2) | 64 | (4.1) | 79 | (2.8) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Onychalgia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Onychoclasis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Onycholysis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Onychomadesis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pain of skin | 1 | (0.1) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Palmar erythema | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Palmar-plantar erythrodysaesthesia syndrome | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Panniculitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Papule | 0 | (0.0) | 1 | (0.1) | 17 | (1.1) | 18 | (0.6) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 16 | (1.0) | 17 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Parapsoriasis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pemphigoid | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Penile ulceration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Petechiae | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Photosensitivity reaction | 1 | (0.1) | 2 | (0.2) | 16 | (1.0) | 18 | (0.6) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 16 | (1.0) | 18 | (0.6) |
| Pigmentation disorder | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Pityriasis rosea | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Prurigo | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Prurigo | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pruritus | 73 | (10.7) | 148 | (12.0) | 414 | (26.4) | 562 | (20.1) |
| Grade 1 | 54 | (7.9) | 119 | (9.7) | 362 | (23.1) | 481 | (17.2) |
| Grade 2 | 19 | (2.8) | 29 | (2.4) | 48 | (3.1) | 77 | (2.8) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Pruritus allergic | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pruritus generalised | 2 | (0.3) | 4 | (0.3) | 18 | (1.1) | 22 | (0.8) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 17 | (1.1) | 21 | (0.8) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pseudofolliculitis barbae | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Psoriasis | 5 | (0.7) | 9 | (0.7) | 11 | (0.7) | 20 | (0.7) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Purpura | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pustular psoriasis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rash | 94 | (13.8) | 161 | (13.1) | 338 | (21.6) | 499 | (17.8) |
| Grade 1 | 71 | (10.4) | 128 | (10.4) | 281 | (17.9) | 409 | (14.6) |
| Grade 2 | 21 | (3.1) | 29 | (2.4) | 52 | (3.3) | 81 | (2.9) |
| Grade 3 | 2 | (0.3) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Rash erythematous | 0 | (0.0) | 2 | (0.2) | 14 | (0.9) | 16 | (0.6) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 10 | (0.6) | 12 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rash follicular | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rash generalised | 0 | (0.0) | 3 | (0.2) | 17 | (1.1) | 20 | (0.7) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 11 | (0.7) | 14 | (0.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rash macular | 2 | (0.3) | 6 | (0.5) | 16 | (1.0) | 22 | (0.8) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 14 | (0.9) | 19 | (0.7) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Rash maculo-papular | 11 | (1.6) | 24 | (1.9) | 76 | (4.9) | 100 | (3.6) |
| Grade 1 | 8 | (1.2) | 18 | (1.5) | 50 | (3.2) | 68 | (2.4) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 21 | (1.3) | 25 | (0.9) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Rash papular | 1 | (0.1) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Rash pruritic | 7 | (1.0) | 10 | (0.8) | 25 | (1.6) | 35 | (1.3) |
| Grade 1 | 6 | (0.9) | 7 | (0.6) | 20 | (1.3) | 27 | (1.0) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rash vesicular | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rosacea | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Scab | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Scar pain | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Sebaceous gland disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Seborrhoea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seborrhoeic dermatitis | 4 | (0.6) | 6 | (0.5) | 5 | (0.3) | 11 | (0.4) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Skin burning sensation | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Skin depigmentation | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Skin discolouration | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Skin disorder | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Skin exfoliation | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 8 | (0.5) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Skin fissures | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin haemorrhage | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin hyperpigmentation | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| Skin hypertrophy | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin hypopigmentation | 1 | (0.1) | 2 | (0.2) | 32 | (2.0) | 34 | (1.2) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Skin hypopigmentation | 1 | (0.1) | 2 | (0.2) | 32 | (2.0) | 34 | (1.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 28 | (1.8) | 30 | (1.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin irritation | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Skin lesion | 6 | (0.9) | 11 | (0.9) | 39 | (2.5) | 50 | (1.8) |
| Grade 1 | 6 | (0.9) | 9 | (0.7) | 34 | (2.2) | 43 | (1.5) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin maceration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin mass | 1 | (0.1) | 2 | (0.2) | 11 | (0.7) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin plaque | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin reaction | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Skin striae | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin ulcer | 4 | (0.6) | 5 | (0.4) | 14 | (0.9) | 19 | (0.7) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 10 | (0.6) | 13 | (0.5) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Skin ulcer haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Solar dermatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stasis dermatitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Stevens-Johnson syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Swelling face | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Telangiectasia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Toxic skin eruption | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Transient acantholytic dermatosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urticaria | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Urticaria | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urticaria papular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vitiligo | 1 | (0.1) | 1 | (0.1) | 170 | (10.8) | 171 | (6.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 146 | (9.3) | 147 | (5.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 24 | (1.5) | 24 | (0.9) |
| Xanthelasma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Xeroderma | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| **Social circumstances** | **0** | **(0.0)** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.0)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Activities of daily living impaired | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Surgical and medical procedures** | **0** | **(0.0)** | **4** | **(0.3)** | **1** | **(0.1)** | **5** | **(0.2)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Astringent therapy | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mitral valve replacement | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin neoplasm excision | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth extraction | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Vascular disorders** | **86** | **(12.6)** | **156** | **(12.7)** | **254** | **(16.2)** | **410** | **(14.6)** |
| Grade 1 | 31 | (4.5) | 58 | (4.7) | 133 | (8.5) | 191 | (6.8) |
| Grade 2 | 29 | (4.3) | 58 | (4.7) | 77 | (4.9) | 135 | (4.8) |
| Grade 3 | 23 | (3.4) | 34 | (2.8) | 40 | (2.6) | 74 | (2.6) |
| Grade 4 | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 5 | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Aortic stenosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Aortic stenosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aortic thrombosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Arterial stenosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Arterial thrombosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Deep vein thrombosis | 6 | (0.9) | 24 | (1.9) | 16 | (1.0) | 40 | (1.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 6 | (0.9) | 22 | (1.8) | 9 | (0.6) | 31 | (1.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Embolism | 5 | (0.7) | 12 | (1.0) | 5 | (0.3) | 17 | (0.6) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 2 | (0.3) | 6 | (0.5) | 0 | (0.0) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Embolism venous | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Extremity necrosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Femoral artery occlusion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Flushing | 5 | (0.7) | 6 | (0.5) | 16 | (1.0) | 22 | (0.8) |
| Grade 1 | 4 | (0.6) | 5 | (0.4) | 16 | (1.0) | 21 | (0.8) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haematoma | 2 | (0.3) | 4 | (0.3) | 12 | (0.8) | 16 | (0.6) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhage | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Haemorrhagic infarction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hot flush | 10 | (1.5) | 17 | (1.4) | 35 | (2.2) | 52 | (1.9) |
| Grade 1 | 9 | (1.3) | 16 | (1.3) | 35 | (2.2) | 51 | (1.8) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypertension | 25 | (3.7) | 40 | (3.2) | 66 | (4.2) | 106 | (3.8) |
| Grade 1 | 6 | (0.9) | 10 | (0.8) | 14 | (0.9) | 24 | (0.9) |
| Grade 2 | 9 | (1.3) | 17 | (1.4) | 33 | (2.1) | 50 | (1.8) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hypertension | 25 | (3.7) | 40 | (3.2) | 66 | (4.2) | 106 | (3.8) |
| Grade 3 | 10 | (1.5) | 13 | (1.1) | 19 | (1.2) | 32 | (1.1) |
| Hypertensive crisis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypotension | 17 | (2.5) | 26 | (2.1) | 40 | (2.6) | 66 | (2.4) |
| Grade 1 | 8 | (1.2) | 13 | (1.1) | 26 | (1.7) | 39 | (1.4) |
| Grade 2 | 7 | (1.0) | 10 | (0.8) | 10 | (0.6) | 20 | (0.7) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Intermittent claudication | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Intra-abdominal haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ischaemia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Jugular vein thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphatic fistula | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphoedema | 0 | (0.0) | 0 | (0.0) | 30 | (1.9) | 30 | (1.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 21 | (1.3) | 21 | (0.8) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 8 | (0.5) | 8 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Orthostatic hypotension | 1 | (0.1) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Pallor | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Pelvic venous thrombosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Peripheral arterial occlusive disease | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Peripheral coldness | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral embolism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral ischaemia | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Peripheral vascular disorder | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Peripheral venous disease | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Phlebitis | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Poor venous access | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Prehypertension | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Raynaud's phenomenon | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Shock haemorrhagic | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Subclavian vein thrombosis | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Superior vena cava occlusion | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Superior vena cava stenosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Superior vena cava syndrome | 4 | (0.6) | 5 | (0.4) | 0 | (0.0) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombophlebitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombophlebitis superficial | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombosis | 4 | (0.6) | 7 | (0.6) | 0 | (0.0) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Varicophlebitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Varicose vein | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |



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# Subjects With Adverse Events by Maximum Toxicity Grade
# (Incidence >0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Vasculitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vasospasm | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vein disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vena cava thrombosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Venous thrombosis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Venous thrombosis limb | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **NULL** | **0** | **(0.0)** | **2** | **(0.2)** | **0** | **(0.0)** | **2** | **(0.1)** |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| NULL | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |

Every subject is counted a single time for each applicable specific adverse event. A subject with multiple adverse events within a system organ class is counted a single time for that system organ class.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns is greater than or equal to the incidence specified in the report title, after rounding.

Only the highest reported grade of a given adverse event is counted for the individual subject.

Grades are based on NCI CTCAE version 4.0.

MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted].

(MK-3475 PN002 Database Cutoff Date: [redacted].

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).



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## 付録 2.7.4- 31　　副作用（いずれかの投与群で発現割合 1%以上）

### 001 試験＋002 試験＋006 試験＋010 試験

### MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

### Subjects With Drug-Related Adverse Events
### (Incidence ≥ 1% in One or More Treatment Groups)
### PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
### (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Subjects in population | 682 | | 1,232 | | 1,567 | | 2,799 | |
| with one or more adverse events | 441 | (64.7) | 821 | (66.6) | 1,241 | (79.2) | 2,062 | (73.7) |
| with no adverse events | 241 | (35.3) | 411 | (33.4) | 326 | (20.8) | 737 | (26.3) |
| **Blood and lymphatic system disorders** | **41** | **(6.0)** | **68** | **(5.5)** | **89** | **(5.7)** | **157** | **(5.6)** |
| Anaemia | 24 | (3.5) | 45 | (3.7) | 49 | (3.1) | 94 | (3.4) |
| Thrombocytopenia | 4 | (0.6) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| **Cardiac disorders** | **8** | **(1.2)** | **14** | **(1.1)** | **10** | **(0.6)** | **24** | **(0.9)** |
| **Endocrine disorders** | **71** | **(10.4)** | **119** | **(9.7)** | **172** | **(11.0)** | **291** | **(10.4)** |
| Hyperthyroidism | 25 | (3.7) | 35 | (2.8) | 47 | (3.0) | 82 | (2.9) |
| Hypothyroidism | 48 | (7.0) | 88 | (7.1) | 125 | (8.0) | 213 | (7.6) |
| **Eye disorders** | **18** | **(2.6)** | **29** | **(2.4)** | **96** | **(6.1)** | **125** | **(4.5)** |
| Dry eye | 10 | (1.5) | 11 | (0.9) | 20 | (1.3) | 31 | (1.1) |
| **Gastrointestinal disorders** | **153** | **(22.4)** | **278** | **(22.6)** | **520** | **(33.2)** | **798** | **(28.5)** |
| Abdominal pain | 7 | (1.0) | 13 | (1.1) | 52 | (3.3) | 65 | (2.3) |
| Abdominal pain upper | 1 | (0.1) | 3 | (0.2) | 23 | (1.5) | 26 | (0.9) |
| Colitis | 5 | (0.7) | 10 | (0.8) | 27 | (1.7) | 37 | (1.3) |
| Constipation | 23 | (3.4) | 34 | (2.8) | 56 | (3.6) | 90 | (3.2) |
| Diarrhoea | 46 | (6.7) | 93 | (7.5) | 250 | (16.0) | 343 | (12.3) |
| Dry mouth | 8 | (1.2) | 17 | (1.4) | 60 | (3.8) | 77 | (2.8) |
| Nausea | 68 | (10.0) | 109 | (8.8) | 195 | (12.4) | 304 | (10.9) |
| Stomatitis | 20 | (2.9) | 29 | (2.4) | 4 | (0.3) | 33 | (1.2) |
| Vomiting | 25 | (3.7) | 40 | (3.2) | 67 | (4.3) | 107 | (3.8) |
| **General disorders and administration site conditions** | **180** | **(26.4)** | **355** | **(28.8)** | **720** | **(45.9)** | **1,075** | **(38.4)** |
| Asthenia | 39 | (5.7) | 70 | (5.7) | 148 | (9.4) | 218 | (7.8) |
| Chills | 6 | (0.9) | 16 | (1.3) | 62 | (4.0) | 78 | (2.8) |
| Fatigue | 95 | (13.9) | 199 | (16.2) | 479 | (30.6) | 678 | (24.2) |
| Influenza like illness | 7 | (1.0) | 13 | (1.1) | 33 | (2.1) | 46 | (1.6) |
| Malaise | 14 | (2.1) | 15 | (1.2) | 8 | (0.5) | 23 | (0.8) |
| Mucosal inflammation | 2 | (0.3) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| Oedema peripheral | 9 | (1.3) | 18 | (1.5) | 36 | (2.3) | 54 | (1.9) |
| Pyrexia | 24 | (3.5) | 49 | (4.0) | 77 | (4.9) | 126 | (4.5) |



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## Subjects With Drug-Related Adverse Events
## (Incidence ≥ 1% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Hepatobiliary disorders** | **7** | **(1.0)** | **9** | **(0.7)** | **23** | **(1.5)** | **32** | **(1.1)** |
| **Immune system disorders** | **3** | **(0.4)** | **8** | **(0.6)** | **18** | **(1.1)** | **26** | **(0.9)** |
| **Infections and infestations** | **30** | **(4.4)** | **51** | **(4.1)** | 77 | **(4.9)** | **128** | **(4.6)** |
| Pneumonia | 10 | (1.5) | 13 | (1.1) | 3 | (0.2) | 16 | (0.6) |
| **Injury, poisoning and procedural complications** | **9** | **(1.3)** | **20** | **(1.6)** | **20** | **(1.3)** | **40** | **(1.4)** |
| Infusion related reaction | 5 | (0.7) | 15 | (1.2) | 12 | (0.8) | 27 | (1.0) |
| **Investigations** | **88** | **(12.9)** | **155** | **(12.6)** | **231** | **(14.7)** | **386** | **(13.8)** |
| Alanine aminotransferase increased | 24 | (3.5) | 37 | (3.0) | 60 | (3.8) | 97 | (3.5) |
| Aspartate aminotransferase increased | 17 | (2.5) | 33 | (2.7) | 61 | (3.9) | 94 | (3.4) |
| Blood alkaline phosphatase increased | 11 | (1.6) | 17 | (1.4) | 20 | (1.3) | 37 | (1.3) |
| Blood bilirubin increased | 5 | (0.7) | 7 | (0.6) | 19 | (1.2) | 26 | (0.9) |
| Blood creatinine increased | 13 | (1.9) | 17 | (1.4) | 18 | (1.1) | 35 | (1.3) |
| Blood thyroid stimulating hormone increased | 7 | (1.0) | 14 | (1.1) | 15 | (1.0) | 29 | (1.0) |
| Lymphocyte count decreased | 4 | (0.6) | 6 | (0.5) | 18 | (1.1) | 24 | (0.9) |
| Weight decreased | 15 | (2.2) | 34 | (2.8) | 26 | (1.7) | 60 | (2.1) |
| **Metabolism and nutrition disorders** | **119** | **(17.4)** | **190** | **(15.4)** | **198** | **(12.6)** | **388** | **(13.9)** |
| Decreased appetite | 79 | (11.6) | 135 | (11.0) | 120 | (7.7) | 255 | (9.1) |
| Hypertriglyceridaemia | 10 | (1.5) | 12 | (1.0) | 12 | (0.8) | 24 | (0.9) |
| Hypocalcaemia | 3 | (0.4) | 4 | (0.3) | 17 | (1.1) | 21 | (0.8) |
| Hypophosphataemia | 3 | (0.4) | 4 | (0.3) | 16 | (1.0) | 20 | (0.7) |



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## Subjects With Drug-Related Adverse Events
## (Incidence ≥ 1% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Musculoskeletal and connective tissue disorders** | **77** | **(11.3)** | **162** | **(13.1)** | **368** | **(23.5)** | **530** | **(18.9)** |
| Arthralgia | 32 | (4.7) | 81 | (6.6) | 200 | (12.8) | 281 | (10.0) |
| Arthritis | 6 | (0.9) | 10 | (0.8) | 16 | (1.0) | 26 | (0.9) |
| Back pain | 9 | (1.3) | 15 | (1.2) | 32 | (2.0) | 47 | (1.7) |
| Muscle spasms | 5 | (0.7) | 11 | (0.9) | 25 | (1.6) | 36 | (1.3) |
| Muscular weakness | 2 | (0.3) | 2 | (0.2) | 20 | (1.3) | 22 | (0.8) |
| Musculoskeletal pain | 8 | (1.2) | 15 | (1.2) | 16 | (1.0) | 31 | (1.1) |
| Musculoskeletal stiffness | 1 | (0.1) | 4 | (0.3) | 20 | (1.3) | 24 | (0.9) |
| Myalgia | 19 | (2.8) | 36 | (2.9) | 110 | (7.0) | 146 | (5.2) |
| Pain in extremity | 6 | (0.9) | 9 | (0.7) | 35 | (2.2) | 44 | (1.6) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **4** | **(0.6)** | **6** | **(0.5)** | **19** | **(1.2)** | **25** | **(0.9)** |
| **Nervous system disorders** | **60** | **(8.8)** | **94** | **(7.6)** | **223** | **(14.2)** | **317** | **(11.3)** |
| Dizziness | 11 | (1.6) | 16 | (1.3) | 30 | (1.9) | 46 | (1.6) |
| Dysgeusia | 11 | (1.6) | 14 | (1.1) | 31 | (2.0) | 45 | (1.6) |
| Headache | 14 | (2.1) | 24 | (1.9) | 87 | (5.6) | 111 | (4.0) |
| Neuropathy peripheral | 5 | (0.7) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| **Psychiatric disorders** | **11** | **(1.6)** | **14** | **(1.1)** | **52** | **(3.3)** | **66** | **(2.4)** |
| Insomnia | 6 | (0.9) | 9 | (0.7) | 17 | (1.1) | 26 | (0.9) |
| **Renal and urinary disorders** | **11** | **(1.6)** | **18** | **(1.5)** | **25** | **(1.6)** | **43** | **(1.5)** |
| **Reproductive system and breast disorders** | **4** | **(0.6)** | **6** | **(0.5)** | **20** | **(1.3)** | **26** | **(0.9)** |
| **Respiratory, thoracic and mediastinal disorders** | **74** | **(10.9)** | **142** | **(11.5)** | **209** | **(13.3)** | **351** | **(12.5)** |
| Cough | 11 | (1.6) | 24 | (1.9) | 88 | (5.6) | 112 | (4.0) |
| Dyspnoea | 21 | (3.1) | 43 | (3.5) | 66 | (4.2) | 109 | (3.9) |
| Pneumonitis | 26 | (3.8) | 47 | (3.8) | 33 | (2.1) | 80 | (2.9) |



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# Subjects With Drug-Related Adverse Events
# (Incidence ≥ 1% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **148** | **(21.7)** | **282** | **(22.9)** | **738** | **(47.1)** | **1,020** | **(36.4)** |
| Alopecia | 5 | (0.7) | 8 | (0.6) | 16 | (1.0) | 24 | (0.9) |
| Dermatitis acneiform | 2 | (0.3) | 15 | (1.2) | 13 | (0.8) | 28 | (1.0) |
| Dry skin | 18 | (2.6) | 37 | (3.0) | 53 | (3.4) | 90 | (3.2) |
| Eczema | 4 | (0.6) | 5 | (0.4) | 25 | (1.6) | 30 | (1.1) |
| Erythema | 3 | (0.4) | 6 | (0.5) | 40 | (2.6) | 46 | (1.6) |
| Hair colour changes | 0 | (0.0) | 0 | (0.0) | 16 | (1.0) | 16 | (0.6) |
| Night sweats | 4 | (0.6) | 5 | (0.4) | 30 | (1.9) | 35 | (1.3) |
| Pruritus | 57 | (8.4) | 116 | (9.4) | 351 | (22.4) | 467 | (16.7) |
| Pruritus generalised | 2 | (0.3) | 3 | (0.2) | 16 | (1.0) | 19 | (0.7) |
| Rash | 73 | (10.7) | 123 | (10.0) | 263 | (16.8) | 386 | (13.8) |
| Rash maculo-papular | 9 | (1.3) | 17 | (1.4) | 59 | (3.8) | 76 | (2.7) |
| Rash pruritic | 5 | (0.7) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| Skin hypopigmentation | 0 | (0.0) | 1 | (0.1) | 29 | (1.9) | 30 | (1.1) |
| Vitiligo | 1 | (0.1) | 1 | (0.1) | 158 | (10.1) | 159 | (5.7) |
| **Vascular disorders** | **16** | **(2.3)** | **33** | **(2.7)** | **48** | **(3.1)** | **81** | **(2.9)** |
| Hot flush | 1 | (0.1) | 5 | (0.4) | 17 | (1.1) | 22 | (0.8) |

Every subject is counted a single time for each applicable row and column.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted].

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).



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## 付録 2.7.4- 32　　副作用（いずれかの投与群で発現割合 0%超）

### 001 試験＋002 試験＋006 試験＋010 試験

### MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

### Subjects With Drug-Related Adverse Events
### (Incidence > 0% in One or More Treatment Groups)
### PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
### (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Subjects in population | 682 | | 1,232 | | 1,567 | | 2,799 | |
| with one or more adverse events | 441 | (64.7) | 821 | (66.6) | 1,241 | (79.2) | 2,062 | (73.7) |
| with no adverse events | 241 | (35.3) | 411 | (33.4) | 326 | (20.8) | 737 | (26.3) |
| **Blood and lymphatic system disorders** | **41** | **(6.0)** | **68** | **(5.5)** | **89** | **(5.7)** | **157** | **(5.6)** |
| Anaemia | 24 | (3.5) | 45 | (3.7) | 49 | (3.1) | 94 | (3.4) |
| Autoimmune haemolytic anaemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eosinophilia | 2 | (0.3) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Haemolytic anaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Immune thrombocytopenic purpura | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iron deficiency anaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Leukaemoid reaction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Leukocytosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Leukopenia | 4 | (0.6) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Lymph node pain | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lymphadenitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Lymphopenia | 6 | (0.9) | 6 | (0.5) | 8 | (0.5) | 14 | (0.5) |
| Microcytic anaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutropenia | 2 | (0.3) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Neutrophilia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pancytopenia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Splenomegaly | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombocytopenia | 4 | (0.6) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| **Cardiac disorders** | **8** | **(1.2)** | **14** | **(1.1)** | **10** | **(0.6)** | **24** | **(0.9)** |
| Acute myocardial infarction | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Angina unstable | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Arrhythmia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Atrial fibrillation | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Atrioventricular block complete | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardiac tamponade | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardio-respiratory arrest | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cyanosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myocardial infarction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Cardiac disorders** | **8** | **(1.2)** | **14** | **(1.1)** | **10** | **(0.6)** | **24** | **(0.9)** |
| Palpitations | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Pericardial effusion | 2 | (0.3) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Pericarditis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tachycardia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Congenital, familial and genetic disorders** | **0** | **(0.0)** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.0)** |
| Ichthyosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Ear and labyrinth disorders** | **3** | **(0.4)** | **6** | **(0.5)** | **13** | **(0.8)** | **19** | **(0.7)** |
| External ear pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hearing impaired | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hyperacusis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tinnitus | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vertigo | 2 | (0.3) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Vertigo positional | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Endocrine disorders** | **71** | **(10.4)** | **119** | **(9.7)** | **172** | **(11.0)** | **291** | **(10.4)** |
| Adrenal insufficiency | 3 | (0.4) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Autoimmune thyroiditis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Endocrine disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperparathyroidism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperthyroidism | 25 | (3.7) | 35 | (2.8) | 47 | (3.0) | 82 | (2.9) |
| Hypophysitis | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Hypopituitarism | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Hypothalamo-pituitary disorder | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypothyroidism | 48 | (7.0) | 88 | (7.1) | 125 | (8.0) | 213 | (7.6) |
| Myxoedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Primary hypothyroidism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Secondary adrenocortical insufficiency | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroiditis | 2 | (0.3) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| **Eye disorders** | **18** | **(2.6)** | **29** | **(2.4)** | **96** | **(6.1)** | **125** | **(4.5)** |
| Abnormal sensation in eye | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Asthenopia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Eye disorders** | **18** | **(2.6)** | **29** | **(2.4)** | **96** | **(6.1)** | **125** | **(4.5)** |
| Blepharitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cataract | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Conjunctival haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Conjunctival hyperaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Corneal irritation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diplopia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dry eye | 10 | (1.5) | 11 | (0.9) | 20 | (1.3) | 31 | (1.1) |
| Eczema eyelids | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Erythema of eyelid | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye discharge | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eye disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Eye inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye irritation | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Eye oedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eye pain | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Eye pruritus | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Eye swelling | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Eyelash discolouration | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Eyelid exfoliation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid ptosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eyelid rash | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Eyelids pruritus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Foreign body sensation in eyes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Growth of eyelashes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypopigmentation of eyelid | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iridocyclitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Iritis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Keratitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lacrimation increased | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Macular degeneration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ocular discomfort | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Ocular hyperaemia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Papilloedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Periorbital oedema | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Photophobia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Photopsia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Eye disorders** | **18** | **(2.6)** | **29** | **(2.4)** | **96** | **(6.1)** | **125** | **(4.5)** |
| Scleritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Uveitis | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Vision blurred | 2 | (0.3) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Visual impairment | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Vitreous floaters | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| **Gastrointestinal disorders** | **153** | **(22.4)** | **278** | **(22.6)** | **520** | **(33.2)** | **798** | **(28.5)** |
| Abdominal discomfort | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Abdominal distension | 3 | (0.4) | 5 | (0.4) | 14 | (0.9) | 19 | (0.7) |
| Abdominal pain | 7 | (1.0) | 13 | (1.1) | 52 | (3.3) | 65 | (2.3) |
| Abdominal pain lower | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Abdominal pain upper | 1 | (0.1) | 3 | (0.2) | 23 | (1.5) | 26 | (0.9) |
| Aerophagia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aphthous stomatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aptyalism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ascites | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Autoimmune colitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune pancreatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chapped lips | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cheilitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Colitis | 5 | (0.7) | 10 | (0.8) | 27 | (1.7) | 37 | (1.3) |
| Colitis microscopic | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Constipation | 23 | (3.4) | 34 | (2.8) | 56 | (3.6) | 90 | (3.2) |
| Defaecation urgency | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Diarrhoea | 46 | (6.7) | 93 | (7.5) | 250 | (16.0) | 343 | (12.3) |
| Dry mouth | 8 | (1.2) | 17 | (1.4) | 60 | (3.8) | 77 | (2.8) |
| Duodenitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dyspepsia | 2 | (0.3) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Dysphagia | 3 | (0.4) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Enteritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Enterocolitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Epigastric discomfort | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Faecal volume increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Faeces hard | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Faeces soft | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Flatulence | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Food poisoning | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Drug-Related Adverse Events
# (Incidence > 0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Gastrointestinal disorders** | **153** | **(22.4)** | **278** | **(22.6)** | **520** | **(33.2)** | **798** | **(28.5)** |
| Frequent bowel movements | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Gastritis | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Gastrointestinal disorder | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Gastrointestinal pain | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal sounds abnormal | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Gastrooesophageal reflux disease | 2 | (0.3) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Gingival bleeding | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Gingival pain | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Glossitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Haemorrhoids | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Ileus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Impaired gastric emptying | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Inguinal hernia | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Intestinal obstruction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Intussusception | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Irritable bowel syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Leukoplakia oral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip oedema | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Lip swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mouth ulceration | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Mucous stools | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nausea | 68 | (10.0) | 109 | (8.8) | 195 | (12.4) | 304 | (10.9) |
| Odynophagia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Oesophagitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral mucosal blistering | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral pain | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Pancreatitis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Pancreatitis chronic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Periodontal disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rectal haemorrhage | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Regurgitation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Retching | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Salivary gland disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Gastrointestinal disorders** | **153** | **(22.4)** | **278** | **(22.6)** | **520** | **(33.2)** | **798** | **(28.5)** |
| Sensitivity of teeth | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Small intestinal perforation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stomatitis | 20 | (2.9) | 29 | (2.4) | 4 | (0.3) | 33 | (1.2) |
| Tongue discolouration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth demineralisation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth disorder | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Toothache | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vomiting | 25 | (3.7) | 40 | (3.2) | 67 | (4.3) | 107 | (3.8) |
| **General disorders and administration site conditions** | **180** | **(26.4)** | **355** | **(28.8)** | **720** | **(45.9)** | **1,075** | **(38.4)** |
| Adverse drug reaction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Asthenia | 39 | (5.7) | 70 | (5.7) | 148 | (9.4) | 218 | (7.8) |
| Axillary pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Chest discomfort | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Chest pain | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Chills | 6 | (0.9) | 16 | (1.3) | 62 | (4.0) | 78 | (2.8) |
| Enanthema | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Face oedema | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Facial pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Fatigue | 95 | (13.9) | 199 | (16.2) | 479 | (30.6) | 678 | (24.2) |
| Feeling cold | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Feeling hot | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Fibrosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gait disturbance | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| General physical health deterioration | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Generalised oedema | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Hyperthermia | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Hypothermia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Inflammation | 0 | (0.0) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Inflammatory pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Influenza like illness | 7 | (1.0) | 13 | (1.1) | 33 | (2.1) | 46 | (1.6) |
| Infusion site extravasation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infusion site pain | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infusion site swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **General disorders and administration site conditions** | **180** | **(26.4)** | **355** | **(28.8)** | **720** | **(45.9)** | **1,075** | **(38.4)** |
| Injection site discomfort | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Injection site extravasation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Injection site reaction | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Localised oedema | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Malaise | 14 | (2.1) | 15 | (1.2) | 8 | (0.5) | 23 | (0.8) |
| Mucosal discolouration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mucosal dryness | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mucosal inflammation | 2 | (0.3) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| Nodule | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Non-cardiac chest pain | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Oedema | 1 | (0.1) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Oedema peripheral | 9 | (1.3) | 18 | (1.5) | 36 | (2.3) | 54 | (1.9) |
| Pain | 4 | (0.6) | 9 | (0.7) | 12 | (0.8) | 21 | (0.8) |
| Performance status decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral swelling | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Pyrexia | 24 | (3.5) | 49 | (4.0) | 77 | (4.9) | 126 | (4.5) |
| Serositis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Systemic inflammatory response syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Temperature intolerance | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Thirst | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Xerosis | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| **Hepatobiliary disorders** | **7** | **(1.0)** | **9** | **(0.7)** | **23** | **(1.5)** | **32** | **(1.1)** |
| Autoimmune hepatitis | 3 | (0.4) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Cholangitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cholestasis | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Drug-induced liver injury | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hepatic function abnormal | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hepatic pain | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hepatic steatosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hepatitis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Hepatobiliary disorders** | **7** | **(1.0)** | **9** | **(0.7)** | **23** | **(1.5)** | **32** | **(1.1)** |
| Hepatocellular injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatotoxicity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperbilirubinaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Liver disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Immune system disorders** | **3** | **(0.4)** | **8** | **(0.6)** | **18** | **(1.1)** | **26** | **(0.9)** |
| Allergy to animal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Anaphylactic reaction | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Anaphylactoid reaction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Atopy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contrast media allergy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cytokine release syndrome | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Drug hypersensitivity | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Hypersensitivity | 1 | (0.1) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Immune system disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sarcoidosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seasonal allergy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Serum sickness | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Infections and infestations** | **30** | **(4.4)** | **51** | **(4.1)** | **77** | **(4.9)** | **128** | **(4.6)** |
| Anal abscess | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bacterial sepsis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Candida infection | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Cellulitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chronic sinusitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clostridium difficile infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Conjunctivitis | 2 | (0.3) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Cystitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dermatophytosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diverticulitis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Encephalitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erysipelas | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Folliculitis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Infections and infestations** | **30** | **(4.4)** | **51** | **(4.1)** | **77** | **(4.9)** | **128** | **(4.6)** |
| Fungal infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Fungal skin infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Furuncle | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastroenteritis viral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Herpes ophthalmic | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Herpes zoster | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Hordeolum | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Influenza | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Laryngitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Listeriosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Liver abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lower respiratory tract infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lung infection | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Lymph gland infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphangitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Meningitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis listeria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mucosal infection | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Nail infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nasal herpes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasopharyngitis | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Onychomycosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral candidiasis | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Oral fungal infection | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Oral herpes | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Oral infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Otitis media | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Otitis media acute | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Perichondritis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pharyngitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumonia | 10 | (1.5) | 13 | (1.1) | 3 | (0.2) | 16 | (0.6) |
| Pneumonia viral | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rash pustular | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Respiratory tract infection | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Rhinitis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Sinusitis | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Skin infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Infections and infestations** | **30** | **(4.4)** | **51** | **(4.1)** | **77** | **(4.9)** | **128** | **(4.6)** |
| Staphylococcal infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Staphylococcal skin infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tinea versicolour | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth abscess | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tuberculosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Upper respiratory tract infection | 1 | (0.1) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Urinary tract infection | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Vulvitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal mycotic infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Injury, poisoning and procedural complications** | **9** | **(1.3)** | **20** | **(1.6)** | **20** | **(1.3)** | **40** | **(1.4)** |
| Chillblains | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contusion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Excoriation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fall | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Incision site complication | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infusion related reaction | 5 | (0.7) | 15 | (1.2) | 12 | (0.8) | 27 | (1.0) |
| Injection related reaction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonitis chemical | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Procedural pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Radiation skin injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin abrasion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sunburn | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Investigations** | **88** | **(12.9)** | **155** | **(12.6)** | **231** | **(14.7)** | **386** | **(13.8)** |
| Activated partial thromboplastin time prolonged | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Investigations** | **88** | **(12.9)** | **155** | **(12.6)** | **231** | **(14.7)** | **386** | **(13.8)** |
| Alanine aminotransferase increased | 24 | (3.5) | 37 | (3.0) | 60 | (3.8) | 97 | (3.5) |
| Amylase increased | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Aortic bruit | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aspartate aminotransferase | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Aspartate aminotransferase increased | 17 | (2.5) | 33 | (2.7) | 61 | (3.9) | 94 | (3.4) |
| Autoantibody positive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bilirubin conjugated increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood albumin decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood albumin increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood alkaline phosphatase decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood alkaline phosphatase increased | 11 | (1.6) | 17 | (1.4) | 20 | (1.3) | 37 | (1.3) |
| Blood bicarbonate decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood bilirubin increased | 5 | (0.7) | 7 | (0.6) | 19 | (1.2) | 26 | (0.9) |
| Blood calcium increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Blood chloride decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood cholesterol increased | 3 | (0.4) | 5 | (0.4) | 11 | (0.7) | 16 | (0.6) |
| Blood corticotrophin decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood corticotrophin increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Blood cortisol decreased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Investigations** | **88** | **(12.9)** | **155** | **(12.6)** | **231** | **(14.7)** | **386** | **(13.8)** |
| Blood creatine phosphokinase increased | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Blood creatinine increased | 13 | (1.9) | 17 | (1.4) | 18 | (1.1) | 35 | (1.3) |
| Blood glucose abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood glucose increased | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Blood lactate dehydrogenase increased | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Blood luteinising hormone decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood magnesium decreased | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Blood parathyroid hormone increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood phosphorus decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood prolactin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood testosterone decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood thyroid stimulating hormone decreased | 1 | (0.1) | 6 | (0.5) | 12 | (0.8) | 18 | (0.6) |
| Blood thyroid stimulating hormone increased | 7 | (1.0) | 14 | (1.1) | 15 | (1.0) | 29 | (1.0) |
| Blood triglycerides increased | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Blood urea increased | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Blood uric acid increased | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Body temperature increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| C-reactive protein increased | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Electrocardiogram QT prolonged | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Investigations** | **88** | **(12.9)** | **155** | **(12.6)** | **231** | **(14.7)** | **386** | **(13.8)** |
| Electrocardiogram repolarisation abnormality | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eosinophil count increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Free thyroxine index increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gamma-glutamyltransferase increased | 5 | (0.7) | 6 | (0.5) | 12 | (0.8) | 18 | (0.6) |
| Grip strength decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haematocrit decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haemoglobin decreased | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Hepatic enzyme increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Immunoglobulins increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intraocular pressure decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lipase | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lipase increased | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Liver function test abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphocyte count decreased | 4 | (0.6) | 6 | (0.5) | 18 | (1.1) | 24 | (0.9) |
| Neutrophil count decreased | 2 | (0.3) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Neutrophil count increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Occult blood positive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Platelet count decreased | 4 | (0.6) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Platelet count increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Protein total decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Protein total increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Protein urine present | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Quality of life decreased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Thyroglobulin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine decreased | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Investigations** | **88** | **(12.9)** | **155** | **(12.6)** | **231** | **(14.7)** | **386** | **(13.8)** |
| Thyroxine free decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine free increased | 5 | (0.7) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Thyroxine increased | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Transaminases increased | 1 | (0.1) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Tri-iodothyronine decreased | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Tri-iodothyronine free decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tri-iodothyronine free increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tri-iodothyronine increased | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Weight decreased | 15 | (2.2) | 34 | (2.8) | 26 | (1.7) | 60 | (2.1) |
| Weight increased | 3 | (0.4) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| White blood cell count decreased | 3 | (0.4) | 8 | (0.6) | 6 | (0.4) | 14 | (0.5) |
| White blood cell count increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Metabolism and nutrition disorders** | **119** | **(17.4)** | **190** | **(15.4)** | **198** | **(12.6)** | **388** | **(13.9)** |
| Cell death | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Decreased appetite | 79 | (11.6) | 135 | (11.0) | 120 | (7.7) | 255 | (9.1) |
| Dehydration | 2 | (0.3) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Diabetes mellitus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Electrolyte imbalance | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Failure to thrive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fluid overload | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fluid retention | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gout | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperamylasaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypercalcaemia | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Hypercholesterolaemia | 4 | (0.6) | 6 | (0.5) | 3 | (0.2) | 9 | (0.3) |
| Hyperglycaemia | 3 | (0.4) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Hyperkalaemia | 1 | (0.1) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Hyperlipidaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypermagnesaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |


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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Metabolism and nutrition disorders** | **119** | **(17.4)** | **190** | **(15.4)** | **198** | **(12.6)** | **388** | **(13.9)** |
| Hypertriglyceridaemia | 10 | (1.5) | 12 | (1.0) | 12 | (0.8) | 24 | (0.9) |
| Hyperuricaemia | 2 | (0.3) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Hypoalbuminaemia | 6 | (0.9) | 7 | (0.6) | 4 | (0.3) | 11 | (0.4) |
| Hypocalcaemia | 3 | (0.4) | 4 | (0.3) | 17 | (1.1) | 21 | (0.8) |
| Hypokalaemia | 4 | (0.6) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Hypomagnesaemia | 6 | (0.9) | 10 | (0.8) | 9 | (0.6) | 19 | (0.7) |
| Hyponatraemia | 4 | (0.6) | 8 | (0.6) | 9 | (0.6) | 17 | (0.6) |
| Hypophagia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypophosphataemia | 3 | (0.4) | 4 | (0.3) | 16 | (1.0) | 20 | (0.7) |
| Hypoproteinaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Increased appetite | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Insulin resistant diabetes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iron deficiency | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lactose intolerance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metabolic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Type 1 diabetes mellitus | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Type 2 diabetes mellitus | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Vitamin B12 deficiency | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Musculoskeletal and connective tissue disorders** | **77** | **(11.3)** | **162** | **(13.1)** | **368** | **(23.5)** | **530** | **(18.9)** |
| Ankylosing spondylitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Arthralgia | 32 | (4.7) | 81 | (6.6) | 200 | (12.8) | 281 | (10.0) |
| Arthritis | 6 | (0.9) | 10 | (0.8) | 16 | (1.0) | 26 | (0.9) |
| Arthropathy | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Back pain | 9 | (1.3) | 15 | (1.2) | 32 | (2.0) | 47 | (1.7) |
| Bone pain | 1 | (0.1) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Bursitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chondrocalcinosis pyrophosphate | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fibromyalgia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Flank pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Groin pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Growing pains | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Joint effusion | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Musculoskeletal and connective tissue disorders** | **77** | **(11.3)** | **162** | **(13.1)** | **368** | **(23.5)** | **530** | **(18.9)** |
| Joint range of motion decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Joint stiffness | 2 | (0.3) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Joint swelling | 2 | (0.3) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Kyphosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Limb discomfort | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mobility decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle atrophy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle necrosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle spasms | 5 | (0.7) | 11 | (0.9) | 25 | (1.6) | 36 | (1.3) |
| Muscle tightness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle twitching | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Muscular weakness | 2 | (0.3) | 2 | (0.2) | 20 | (1.3) | 22 | (0.8) |
| Musculoskeletal chest pain | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Musculoskeletal discomfort | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Musculoskeletal pain | 8 | (1.2) | 15 | (1.2) | 16 | (1.0) | 31 | (1.1) |
| Musculoskeletal stiffness | 1 | (0.1) | 4 | (0.3) | 20 | (1.3) | 24 | (0.9) |
| Myalgia | 19 | (2.8) | 36 | (2.9) | 110 | (7.0) | 146 | (5.2) |
| Myopathy | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myositis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Neck pain | 2 | (0.3) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Nodal osteoarthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Osteoarthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pain in extremity | 6 | (0.9) | 9 | (0.7) | 35 | (2.2) | 44 | (1.6) |
| Pain in jaw | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Periarthritis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Plantar fasciitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Polyarthritis | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Polymyalgia rheumatica | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Rhabdomyolysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rheumatoid arthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sjogren's syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Spinal pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Synovitis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Musculoskeletal and connective tissue disorders** | **77** | **(11.3)** | **162** | **(13.1)** | **368** | **(23.5)** | **530** | **(18.9)** |
| Temporomandibular joint syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tendon pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tendonitis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Tenosynovitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Torticollis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **4** | **(0.6)** | **6** | **(0.5)** | **19** | **(1.2)** | **25** | **(0.9)** |
| Acrochordon | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cancer pain | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infected neoplasm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratoacanthoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malignant melanoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malignant neoplasm progression | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Melanocytic naevus | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Metastatic pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Neoplasm swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oncologic complication | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Paraneoplastic syndrome | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Seborrhoeic keratosis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Skin papilloma | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Tumour pain | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| **Nervous system disorders** | **60** | **(8.8)** | **94** | **(7.6)** | **223** | **(14.2)** | **317** | **(11.3)** |
| Ageusia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Amnesia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Amnestic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ataxia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Balance disorder | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Brain oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Burning sensation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Carpal tunnel syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Nervous system disorders** | **60** | **(8.8)** | **94** | **(7.6)** | **223** | **(14.2)** | **317** | **(11.3)** |
| Cerebrovascular accident | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cognitive disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Depressed level of consciousness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Disturbance in attention | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Dizziness | 11 | (1.6) | 16 | (1.3) | 30 | (1.9) | 46 | (1.6) |
| Dysaesthesia | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Dysarthria | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dysgeusia | 11 | (1.6) | 14 | (1.1) | 31 | (2.0) | 45 | (1.6) |
| Encephalopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Epilepsy | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Guillain-Barre syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Headache | 14 | (2.1) | 24 | (1.9) | 87 | (5.6) | 111 | (4.0) |
| Horner's syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperaesthesia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hypersomnia | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Hypoaesthesia | 3 | (0.4) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Hypogeusia | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Hypotonia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Judgement impaired | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lethargy | 3 | (0.4) | 9 | (0.7) | 11 | (0.7) | 20 | (0.7) |
| Loss of consciousness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Memory impairment | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Meningitis noninfective | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myasthenic syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myelitis transverse | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neuralgia | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Neuropathy peripheral | 5 | (0.7) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| Neurotoxicity | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Optic neuritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Paraesthesia | 6 | (0.9) | 10 | (0.8) | 14 | (0.9) | 24 | (0.9) |
| Parosmia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Partial seizures | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral motor neuropathy | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Peripheral sensory neuropathy | 6 | (0.9) | 7 | (0.6) | 5 | (0.3) | 12 | (0.4) |
| Polyneuropathy | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Nervous system disorders** | **60** | **(8.8)** | **94** | **(7.6)** | **223** | **(14.2)** | **317** | **(11.3)** |
| Poor quality sleep | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Presyncope | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Restless legs syndrome | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Sciatica | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seizure | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sensory disturbance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Somnolence | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Syncope | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Toxic leukoencephalopathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Toxic neuropathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tremor | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| **Psychiatric disorders** | **11** | **(1.6)** | **14** | **(1.1)** | **52** | **(3.3)** | **66** | **(2.4)** |
| Affective disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Agitation | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Anxiety | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Apathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Confusional state | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Depression | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Disorientation | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Dysphoria | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hallucination | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Insomnia | 6 | (0.9) | 9 | (0.7) | 17 | (1.1) | 26 | (0.9) |
| Irritability | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Libido decreased | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Middle insomnia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Mood altered | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Personality change | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Phobia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Restlessness | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Sleep disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Trance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Renal and urinary disorders** | **11** | **(1.6)** | **18** | **(1.5)** | **25** | **(1.6)** | **43** | **(1.5)** |
| Acute kidney injury | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Chromaturia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chronic kidney disease | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Cystitis noninfective | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Renal and urinary disorders** | **11** | **(1.6)** | **18** | **(1.5)** | **25** | **(1.6)** | **43** | **(1.5)** |
| Dysuria | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Haematuria | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Micturition urgency | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nocturia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pollakiuria | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Proteinuria | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Renal failure | 2 | (0.3) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Renal impairment | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Tubulointerstitial nephritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Urinary incontinence | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Urinary retention | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urine odour abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Reproductive system and breast disorders** | **4** | **(0.6)** | **6** | **(0.5)** | **20** | **(1.3)** | **26** | **(0.9)** |
| Amenorrhoea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Balanoposthitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Breast pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breast tenderness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dysmenorrhoea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erectile dysfunction | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Genital rash | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gynaecomastia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Haematospermia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Menorrhagia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Nipple pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nipple swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pelvic pain | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Pruritus genital | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Scrotal erythema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal dryness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal pruritus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Respiratory, thoracic and mediastinal disorders** | **74** | **(10.9)** | **142** | **(11.5)** | **209** | **(13.3)** | **351** | **(12.5)** |
| Asthma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchial hyperreactivity | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Respiratory, thoracic and mediastinal disorders** | **74** | **(10.9)** | **142** | **(11.5)** | **209** | **(13.3)** | **351** | **(12.5)** |
| Bronchospasm | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chronic obstructive pulmonary disease | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Cough | 11 | (1.6) | 24 | (1.9) | 88 | (5.6) | 112 | (4.0) |
| Dysphonia | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Dyspnoea | 21 | (3.1) | 43 | (3.5) | 66 | (4.2) | 109 | (3.9) |
| Dyspnoea exertional | 2 | (0.3) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Epistaxis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Haemoptysis | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Hiccups | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Hypoxia | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Interstitial lung disease | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Laryngeal discomfort | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Laryngeal inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lung disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasal congestion | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Nasal dryness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasal mucosal disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oropharyngeal pain | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Painful respiration | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pleural effusion | 5 | (0.7) | 9 | (0.7) | 2 | (0.1) | 11 | (0.4) |
| Pleuritic pain | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Pneumonitis | 26 | (3.8) | 47 | (3.8) | 33 | (2.1) | 80 | (2.9) |
| Pneumothorax | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Productive cough | 0 | (0.0) | 7 | (0.6) | 6 | (0.4) | 13 | (0.5) |
| Pulmonary congestion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pulmonary embolism | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Pulmonary oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Respiration abnormal | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Respiratory tract congestion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rhinitis allergic | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Rhinorrhoea | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Sinus congestion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sneezing | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Sputum discoloured | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tachypnoea | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Throat irritation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Respiratory, thoracic and mediastinal disorders** | **74** | **(10.9)** | **142** | **(11.5)** | **209** | **(13.3)** | **351** | **(12.5)** |
| Throat tightness | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper respiratory tract congestion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper-airway cough syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Wheezing | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| **Skin and subcutaneous tissue disorders** | **148** | **(21.7)** | **282** | **(22.9)** | **738** | **(47.1)** | **1,020** | **(36.4)** |
| Acne | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Actinic keratosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Alopecia | 5 | (0.7) | 8 | (0.6) | 16 | (1.0) | 24 | (0.9) |
| Angioedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blister | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dermatitis | 2 | (0.3) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Dermatitis acneiform | 2 | (0.3) | 15 | (1.2) | 13 | (0.8) | 28 | (1.0) |
| Dermatitis allergic | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dermatitis atopic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatitis bullous | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dermatitis contact | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dermatitis exfoliative | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatitis psoriasiform | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Drug eruption | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Dry skin | 18 | (2.6) | 37 | (3.0) | 53 | (3.4) | 90 | (3.2) |
| Eczema | 4 | (0.6) | 5 | (0.4) | 25 | (1.6) | 30 | (1.1) |
| Eczema asteatotic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eczema nummular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erythema | 3 | (0.4) | 6 | (0.5) | 40 | (2.6) | 46 | (1.6) |
| Erythema multiforme | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Erythema nodosum | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Exfoliative rash | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Generalised erythema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Granuloma skin | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hair colour changes | 0 | (0.0) | 0 | (0.0) | 16 | (1.0) | 16 | (0.6) |
| Hair growth abnormal | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Hair texture abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperhidrosis | 1 | (0.1) | 4 | (0.3) | 14 | (0.9) | 18 | (0.6) |
| Hyperkeratosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypertrichosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **148** | **(21.7)** | **282** | **(22.9)** | **738** | **(47.1)** | **1,020** | **(36.4)** |
| Ichthyosis acquired | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratosis pilaris | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Lichen planus | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Lichen sclerosus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lichenoid keratosis | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Linear IgA disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Macule | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Madarosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mucocutaneous rash | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail discolouration | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nail disorder | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Nail dystrophy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail growth abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail ridging | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail toxicity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutrophilic dermatosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Night sweats | 4 | (0.6) | 5 | (0.4) | 30 | (1.9) | 35 | (1.3) |
| Onychalgia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Onychoclasis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Onycholysis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Onychomadesis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pain of skin | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Palmar-plantar erythrodysaesthesia syndrome | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Panniculitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Papule | 0 | (0.0) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Parapsoriasis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pemphigoid | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Petechiae | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Photosensitivity reaction | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Pigmentation disorder | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Prurigo | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Pruritus | 57 | (8.4) | 116 | (9.4) | 351 | (22.4) | 467 | (16.7) |
| Pruritus allergic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pruritus generalised | 2 | (0.3) | 3 | (0.2) | 16 | (1.0) | 19 | (0.7) |
| Psoriasis | 4 | (0.6) | 6 | (0.5) | 6 | (0.4) | 12 | (0.4) |
| Purpura | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pustular psoriasis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **148** | **(21.7)** | **282** | **(22.9)** | **738** | **(47.1)** | **1,020** | **(36.4)** |
| Rash | 73 | (10.7) | 123 | (10.0) | 263 | (16.8) | 386 | (13.8) |
| Rash erythematous | 0 | (0.0) | 1 | (0.1) | 11 | (0.7) | 12 | (0.4) |
| Rash follicular | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rash generalised | 0 | (0.0) | 2 | (0.2) | 14 | (0.9) | 16 | (0.6) |
| Rash macular | 2 | (0.3) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Rash maculo-papular | 9 | (1.3) | 17 | (1.4) | 59 | (3.8) | 76 | (2.7) |
| Rash papular | 0 | (0.0) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Rash pruritic | 5 | (0.7) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| Rash vesicular | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rosacea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Scab | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sebaceous gland disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seborrhoeic dermatitis | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Skin burning sensation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin depigmentation | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Skin discolouration | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Skin disorder | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin exfoliation | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin fissures | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin hyperpigmentation | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Skin hypopigmentation | 0 | (0.0) | 1 | (0.1) | 29 | (1.9) | 30 | (1.1) |
| Skin irritation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin lesion | 2 | (0.3) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Skin mass | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin plaque | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin reaction | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin ulcer | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Solar dermatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stevens-Johnson syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Swelling face | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Toxic skin eruption | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Transient acantholytic dermatosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urticaria | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Urticaria papular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vitiligo | 1 | (0.1) | 1 | (0.1) | 158 | (10.1) | 159 | (5.7) |
| Xanthelasma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Skin and subcutaneous tissue disorders** | **148** | **(21.7)** | **282** | **(22.9)** | **738** | **(47.1)** | **1,020** | **(36.4)** |
| Xeroderma | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| **Vascular disorders** | **16** | **(2.3)** | **33** | **(2.7)** | **48** | **(3.1)** | **81** | **(2.9)** |
| Arterial thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Deep vein thrombosis | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Embolism | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Flushing | 3 | (0.4) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hot flush | 1 | (0.1) | 5 | (0.4) | 17 | (1.1) | 22 | (0.8) |
| Hyperaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypertension | 5 | (0.7) | 8 | (0.6) | 5 | (0.3) | 13 | (0.5) |
| Hypotension | 3 | (0.4) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Intermittent claudication | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Jugular vein thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphoedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Orthostatic hypotension | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pallor | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral coldness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral ischaemia | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Phlebitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Prehypertension | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Raynaud's phenomenon | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Superior vena cava syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombophlebitis superficial | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Varicophlebitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vasculitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Vasospasm | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Vascular disorders** | **16** | **(2.3)** | **33** | **(2.7)** | **48** | **(3.1)** | **81** | **(2.9)** |
| Venous thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |

Every subject is counted a single time for each applicable row and column.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted]).

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).



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## 付録 2.7.4- 33　　Grade 別の副作用（いずれかの投与群で発現割合 0%超）

001 試験＋002 試験＋006 試験＋010 試験

MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
(Incidence >0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Subjects in population | 682 | | 1,232 | | 1,567 | | 2,799 | |
| with one or more adverse events | 441 | (64.7) | 821 | (66.6) | 1,241 | (79.2) | 2,062 | (73.7) |
| Grade 1 | 152 | (22.3) | 317 | (25.7) | 522 | (33.3) | 839 | (30.0) |
| Grade 2 | 191 | (28.0) | 346 | (28.1) | 491 | (31.3) | 837 | (29.9) |
| Grade 3 | 81 | (11.9) | 131 | (10.6) | 205 | (13.1) | 336 | (12.0) |
| Grade 4 | 11 | (1.6) | 18 | (1.5) | 22 | (1.4) | 40 | (1.4) |
| Grade 5 | 6 | (0.9) | 9 | (0.7) | 1 | (0.1) | 10 | (0.4) |
| with no adverse events | 241 | (35.3) | 411 | (33.4) | 326 | (20.8) | 737 | (26.3) |
| **Blood and lymphatic system disorders** | **41** | **(6.0)** | **68** | **(5.5)** | **89** | **(5.7)** | **157** | **(5.6)** |
| Grade 1 | 13 | (1.9) | 24 | (1.9) | 55 | (3.5) | 79 | (2.8) |
| Grade 2 | 21 | (3.1) | 31 | (2.5) | 19 | (1.2) | 50 | (1.8) |
| Grade 3 | 6 | (0.9) | 11 | (0.9) | 13 | (0.8) | 24 | (0.9) |
| Grade 4 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Anaemia | 24 | (3.5) | 45 | (3.7) | 49 | (3.1) | 94 | (3.4) |
| Grade 1 | 8 | (1.2) | 18 | (1.5) | 27 | (1.7) | 45 | (1.6) |
| Grade 2 | 12 | (1.8) | 21 | (1.7) | 15 | (1.0) | 36 | (1.3) |
| Grade 3 | 4 | (0.6) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Autoimmune haemolytic anaemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eosinophilia | 2 | (0.3) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 11 | (0.7) | 12 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Haemolytic anaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Immune thrombocytopenic purpura | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iron deficiency anaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Leukaemoid reaction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Leukocytosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Leukopenia | 4 | (0.6) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lymph node pain | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lymphadenitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Lymphadenitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphopenia | 6 | (0.9) | 6 | (0.5) | 8 | (0.5) | 14 | (0.5) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 2 | 6 | (0.9) | 6 | (0.5) | 0 | (0.0) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Microcytic anaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutropenia | 2 | (0.3) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutrophilia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pancytopenia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Splenomegaly | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombocytopenia | 4 | (0.6) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| Grade 1 | 3 | (0.4) | 6 | (0.5) | 11 | (0.7) | 17 | (0.6) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Cardiac disorders** | **8** | **(1.2)** | **14** | **(1.1)** | **10** | **(0.6)** | **24** | **(0.9)** |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 4 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 5 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Acute myocardial infarction | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Angina unstable | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Arrhythmia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Atrial fibrillation | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Atrioventricular block complete | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardiac tamponade | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardio-respiratory arrest | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cyanosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myocardial infarction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Palpitations | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pericardial effusion | 2 | (0.3) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Pericarditis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tachycardia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Congenital, familial and genetic disorders** | **0** | **(0.0)** | **1** | **(0.1)** | **0** | **(0.0)** | **1** | **(0.0)** |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Ichthyosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Ear and labyrinth disorders** | **3** | **(0.4)** | **6** | **(0.5)** | **13** | **(0.8)** | **19** | **(0.7)** |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| External ear pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hearing impaired | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperacusis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tinnitus | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Vertigo | 2 | (0.3) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vertigo positional | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Endocrine disorders** | **71** | **(10.4)** | **119** | **(9.7)** | **172** | **(11.0)** | **291** | **(10.4)** |
| Grade 1 | 32 | (4.7) | 41 | (3.3) | 46 | (2.9) | 87 | (3.1) |
| Grade 2 | 35 | (5.1) | 71 | (5.8) | 111 | (7.1) | 182 | (6.5) |
| Grade 3 | 4 | (0.6) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Adrenal insufficiency | 3 | (0.4) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune thyroiditis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Endocrine disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperparathyroidism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperthyroidism | 25 | (3.7) | 35 | (2.8) | 47 | (3.0) | 82 | (2.9) |
| Grade 1 | 18 | (2.6) | 23 | (1.9) | 37 | (2.4) | 60 | (2.1) |
| Grade 2 | 6 | (0.9) | 10 | (0.8) | 8 | (0.5) | 18 | (0.6) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Hypophysitis | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypopituitarism | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Hypothalamo-pituitary disorder | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypothyroidism | 48 | (7.0) | 88 | (7.1) | 125 | (8.0) | 213 | (7.6) |
| Grade 1 | 17 | (2.5) | 24 | (1.9) | 24 | (1.5) | 48 | (1.7) |
| Grade 2 | 31 | (4.5) | 63 | (5.1) | 99 | (6.3) | 162 | (5.8) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Myxoedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Myxoedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Primary hypothyroidism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Secondary adrenocortical insufficiency | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroiditis | 2 | (0.3) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| **Eye disorders** | **18** | **(2.6)** | **29** | **(2.4)** | **96** | **(6.1)** | **125** | **(4.5)** |
| Grade 1 | 14 | (2.1) | 23 | (1.9) | 71 | (4.5) | 94 | (3.4) |
| Grade 2 | 4 | (0.6) | 6 | (0.5) | 23 | (1.5) | 29 | (1.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Abnormal sensation in eye | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Asthenopia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blepharitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cataract | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Conjunctival haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Conjunctival hyperaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Corneal irritation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diplopia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dry eye | 10 | (1.5) | 11 | (0.9) | 20 | (1.3) | 31 | (1.1) |
| Grade 1 | 8 | (1.2) | 9 | (0.7) | 20 | (1.3) | 29 | (1.0) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Eczema eyelids | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Erythema of eyelid | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye discharge | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eye disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Eye inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Eye inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye irritation | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Eye oedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eye pain | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye pruritus | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye swelling | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Eyelash discolouration | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Eyelid exfoliation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid ptosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Eyelid rash | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Eyelids pruritus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Foreign body sensation in eyes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Growth of eyelashes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypopigmentation of eyelid | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iridocyclitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Iritis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lacrimation increased | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Macular degeneration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Macular degeneration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ocular discomfort | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ocular hyperaemia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Papilloedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Periorbital oedema | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Photophobia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Photopsia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Scleritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Uveitis | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Vision blurred | 2 | (0.3) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Visual impairment | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Vitreous floaters | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| **Gastrointestinal disorders** | **153** | **(22.4)** | **278** | **(22.6)** | **520** | **(33.2)** | **798** | **(28.5)** |
| Grade 1 | 98 | (14.4) | 188 | (15.3) | 360 | (23.0) | 548 | (19.6) |
| Grade 2 | 44 | (6.5) | 69 | (5.6) | 104 | (6.6) | 173 | (6.2) |
| Grade 3 | 11 | (1.6) | 21 | (1.7) | 53 | (3.4) | 74 | (2.6) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Abdominal discomfort | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Abdominal distension | 3 | (0.4) | 5 | (0.4) | 14 | (0.9) | 19 | (0.7) |
| Grade 1 | 3 | (0.4) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal pain | 7 | (1.0) | 13 | (1.1) | 52 | (3.3) | 65 | (2.3) |
| Grade 1 | 6 | (0.9) | 9 | (0.7) | 34 | (2.2) | 43 | (1.5) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Abdominal pain | 7 | (1.0) | 13 | (1.1) | 52 | (3.3) | 65 | (2.3) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 17 | (1.1) | 21 | (0.8) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal pain lower | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Abdominal pain upper | 1 | (0.1) | 3 | (0.2) | 23 | (1.5) | 26 | (0.9) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 19 | (1.2) | 21 | (0.8) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Aerophagia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aphthous stomatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aptyalism | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ascites | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune colitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune pancreatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chapped lips | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cheilitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Colitis | 5 | (0.7) | 10 | (0.8) | 27 | (1.7) | 37 | (1.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 3 | 4 | (0.6) | 8 | (0.6) | 17 | (1.1) | 25 | (0.9) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Colitis microscopic | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Constipation | 23 | (3.4) | 34 | (2.8) | 56 | (3.6) | 90 | (3.2) |
| Grade 1 | 18 | (2.6) | 29 | (2.4) | 43 | (2.7) | 72 | (2.6) |
| Grade 2 | 5 | (0.7) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Defaecation urgency | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diarrhoea | 46 | (6.7) | 93 | (7.5) | 250 | (16.0) | 343 | (12.3) |
| Grade 1 | 28 | (4.1) | 64 | (5.2) | 190 | (12.1) | 254 | (9.1) |
| Grade 2 | 16 | (2.3) | 25 | (2.0) | 39 | (2.5) | 64 | (2.3) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Diarrhoea | 46 | (6.7) | 93 | (7.5) | 250 | (16.0) | 343 | (12.3) |
| Grade 3 | 2 | (0.3) | 4 | (0.3) | 21 | (1.3) | 25 | (0.9) |
| Dry mouth | 8 | (1.2) | 17 | (1.4) | 60 | (3.8) | 77 | (2.8) |
| Grade 1 | 5 | (0.7) | 11 | (0.9) | 53 | (3.4) | 64 | (2.3) |
| Grade 2 | 3 | (0.4) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Duodenitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dyspepsia | 2 | (0.3) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Dysphagia | 3 | (0.4) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Enteritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Enterocolitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Epigastric discomfort | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Faecal volume increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Faeces hard | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Faeces soft | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Flatulence | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Food poisoning | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Frequent bowel movements | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastritis | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal disorder | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal pain | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Gastrointestinal sounds abnormal | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Gastrooesophageal reflux disease | 2 | (0.3) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Gingival bleeding | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gingival pain | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Glossitis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Haemorrhoids | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ileus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Impaired gastric emptying | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Inguinal hernia | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Intestinal obstruction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Intussusception | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Irritable bowel syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Leukoplakia oral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lip oedema | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Lip swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mouth ulceration | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Mucous stools | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nausea | 68 | (10.0) | 109 | (8.8) | 195 | (12.4) | 304 | (10.9) |
| Grade 1 | 57 | (8.4) | 90 | (7.3) | 164 | (10.5) | 254 | (9.1) |
| Grade 2 | 8 | (1.2) | 13 | (1.1) | 27 | (1.7) | 40 | (1.4) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Nausea | 68 | (10.0) | 109 | (8.8) | 195 | (12.4) | 304 | (10.9) |
| Grade 3 | 3 | (0.4) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Odynophagia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Oesophagitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral mucosal blistering | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral pain | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pancreatitis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pancreatitis chronic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Periodontal disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rectal haemorrhage | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Regurgitation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Retching | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Salivary gland disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sensitivity of teeth | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Small intestinal perforation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stomatitis | 20 | (2.9) | 29 | (2.4) | 4 | (0.3) | 33 | (1.2) |
| Grade 1 | 12 | (1.8) | 20 | (1.6) | 3 | (0.2) | 23 | (0.8) |
| Grade 2 | 7 | (1.0) | 8 | (0.6) | 1 | (0.1) | 9 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tongue discolouration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth demineralisation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth disorder | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Tooth disorder | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Toothache | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vomiting | 25 | (3.7) | 40 | (3.2) | 67 | (4.3) | 107 | (3.8) |
| Grade 1 | 20 | (2.9) | 32 | (2.6) | 50 | (3.2) | 82 | (2.9) |
| Grade 2 | 4 | (0.6) | 5 | (0.4) | 11 | (0.7) | 16 | (0.6) |
| Grade 3 | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| **General disorders and administration site conditions** | **180** | **(26.4)** | **355** | **(28.8)** | **720** | **(45.9)** | **1,075** | **(38.4)** |
| Grade 1 | 107 | (15.7) | 217 | (17.6) | 475 | (30.3) | 692 | (24.7) |
| Grade 2 | 60 | (8.8) | 119 | (9.7) | 214 | (13.7) | 333 | (11.9) |
| Grade 3 | 13 | (1.9) | 19 | (1.5) | 29 | (1.9) | 48 | (1.7) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Adverse drug reaction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Asthenia | 39 | (5.7) | 70 | (5.7) | 148 | (9.4) | 218 | (7.8) |
| Grade 1 | 22 | (3.2) | 37 | (3.0) | 85 | (5.4) | 122 | (4.4) |
| Grade 2 | 14 | (2.1) | 29 | (2.4) | 55 | (3.5) | 84 | (3.0) |
| Grade 3 | 3 | (0.4) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Axillary pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chest discomfort | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chest pain | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chills | 6 | (0.9) | 16 | (1.3) | 62 | (4.0) | 78 | (2.8) |
| Grade 1 | 5 | (0.7) | 14 | (1.1) | 60 | (3.8) | 74 | (2.6) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Enanthema | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Face oedema | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Facial pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Facial pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Fatigue | 95 | (13.9) | 199 | (16.2) | 479 | (30.6) | 678 | (24.2) |
| Grade 1 | 54 | (7.9) | 122 | (9.9) | 336 | (21.4) | 458 | (16.4) |
| Grade 2 | 31 | (4.5) | 63 | (5.1) | 127 | (8.1) | 190 | (6.8) |
| Grade 3 | 10 | (1.5) | 14 | (1.1) | 16 | (1.0) | 30 | (1.1) |
| Feeling cold | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Feeling hot | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Fibrosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gait disturbance | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| General physical health deterioration | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Generalised oedema | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperthermia | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hypothermia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Inflammation | 0 | (0.0) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Inflammatory pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Influenza like illness | 7 | (1.0) | 13 | (1.1) | 33 | (2.1) | 46 | (1.6) |
| Grade 1 | 6 | (0.9) | 12 | (1.0) | 24 | (1.5) | 36 | (1.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Infusion site extravasation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infusion site pain | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infusion site swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Infusion site swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Injection site discomfort | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Injection site extravasation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Injection site reaction | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Localised oedema | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malaise | 14 | (2.1) | 15 | (1.2) | 8 | (0.5) | 23 | (0.8) |
| Grade 1 | 9 | (1.3) | 10 | (0.8) | 7 | (0.4) | 17 | (0.6) |
| Grade 2 | 5 | (0.7) | 5 | (0.4) | 1 | (0.1) | 6 | (0.2) |
| Mucosal discolouration | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mucosal dryness | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mucosal inflammation | 2 | (0.3) | 8 | (0.6) | 15 | (1.0) | 23 | (0.8) |
| Grade 1 | 2 | (0.3) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nodule | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Non-cardiac chest pain | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Oedema | 1 | (0.1) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Oedema peripheral | 9 | (1.3) | 18 | (1.5) | 36 | (2.3) | 54 | (1.9) |
| Grade 1 | 8 | (1.2) | 17 | (1.4) | 27 | (1.7) | 44 | (1.6) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Pain | 4 | (0.6) | 9 | (0.7) | 12 | (0.8) | 21 | (0.8) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 2 | 3 | (0.4) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Performance status decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral swelling | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Pyrexia | 24 | (3.5) | 49 | (4.0) | 77 | (4.9) | 126 | (4.5) |
| Grade 1 | 19 | (2.8) | 37 | (3.0) | 61 | (3.9) | 98 | (3.5) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pyrexia | 24 | (3.5) | 49 | (4.0) | 77 | (4.9) | 126 | (4.5) |
| Grade 2 | 4 | (0.6) | 11 | (0.9) | 15 | (1.0) | 26 | (0.9) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Serositis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Systemic inflammatory response syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Temperature intolerance | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thirst | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Xerosis | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| **Hepatobiliary disorders** | **7** | **(1.0)** | **9** | **(0.7)** | **23** | **(1.5)** | **32** | **(1.1)** |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 2 | 4 | (0.6) | 6 | (0.5) | 3 | (0.2) | 9 | (0.3) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 11 | (0.7) | 13 | (0.5) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Autoimmune hepatitis | 3 | (0.4) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cholangitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cholestasis | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Drug-induced liver injury | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatic function abnormal | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatic pain | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hepatic steatosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hepatitis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Hepatocellular injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatotoxicity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperbilirubinaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Liver disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Immune system disorders** | **3** | **(0.4)** | **8** | **(0.6)** | **18** | **(1.1)** | **26** | **(0.9)** |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 10 | (0.6) | 13 | (0.5) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Allergy to animal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Anaphylactic reaction | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Anaphylactoid reaction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Atopy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Autoimmune disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contrast media allergy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cytokine release syndrome | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Drug hypersensitivity | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypersensitivity | 1 | (0.1) | 5 | (0.4) | 5 | (0.3) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Immune system disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Immune system disorder | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sarcoidosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seasonal allergy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Serum sickness | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Infections and infestations** | **30** | **(4.4)** | **51** | **(4.1)** | **77** | **(4.9)** | **128** | **(4.6)** |
| Grade 1 | 10 | (1.5) | 16 | (1.3) | 41 | (2.6) | 57 | (2.0) |
| Grade 2 | 13 | (1.9) | 26 | (2.1) | 26 | (1.7) | 52 | (1.9) |
| Grade 3 | 5 | (0.7) | 7 | (0.6) | 10 | (0.6) | 17 | (0.6) |
| Grade 5 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Anal abscess | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bacterial sepsis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Candida infection | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cellulitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chronic sinusitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clostridium difficile infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Conjunctivitis | 2 | (0.3) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Cystitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dermatophytosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diverticulitis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Encephalitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erysipelas | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Erysipelas | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Folliculitis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Fungal infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Fungal skin infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Furuncle | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastroenteritis viral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Herpes ophthalmic | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Herpes zoster | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Hordeolum | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Influenza | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Laryngitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Listeriosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Liver abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lower respiratory tract infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lung infection | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Lymph gland infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphangitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Meningitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis listeria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Mucosal infection | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Mucosal infection | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Nail infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nasal herpes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasopharyngitis | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Onychomycosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oral candidiasis | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Oral fungal infection | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Oral herpes | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Oral infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Otitis media | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Otitis media acute | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Perichondritis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pharyngitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumonia | 10 | (1.5) | 13 | (1.1) | 3 | (0.2) | 16 | (0.6) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 3 | (0.4) | 6 | (0.5) | 0 | (0.0) | 6 | (0.2) |
| Grade 3 | 4 | (0.6) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Grade 5 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pneumonia viral | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rash pustular | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory tract infection | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rhinitis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Sinusitis | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Sinusitis | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Staphylococcal infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Staphylococcal skin infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tinea versicolour | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth abscess | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tuberculosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Upper respiratory tract infection | 1 | (0.1) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Urinary tract infection | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Vulvitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal mycotic infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Injury, poisoning and procedural complications** | **9** | **(1.3)** | **20** | **(1.6)** | **20** | **(1.3)** | **40** | **(1.4)** |
| Grade 1 | 2 | (0.3) | 6 | (0.5) | 11 | (0.7) | 17 | (0.6) |
| Grade 2 | 5 | (0.7) | 12 | (1.0) | 9 | (0.6) | 21 | (0.8) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Chillblains | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contusion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Excoriation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fall | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Incision site complication | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Infusion related reaction | 5 | (0.7) | 15 | (1.2) | 12 | (0.8) | 27 | (1.0) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Grade 2 | 3 | (0.4) | 10 | (0.8) | 8 | (0.5) | 18 | (0.6) |
| Injection related reaction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonitis chemical | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Procedural pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Radiation skin injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin abrasion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sunburn | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tooth fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Investigations** | **88** | **(12.9)** | **155** | **(12.6)** | **231** | **(14.7)** | **386** | **(13.8)** |
| Grade 1 | 47 | (6.9) | 90 | (7.3) | 150 | (9.6) | 240 | (8.6) |
| Grade 2 | 30 | (4.4) | 45 | (3.7) | 55 | (3.5) | 100 | (3.6) |
| Grade 3 | 8 | (1.2) | 15 | (1.2) | 22 | (1.4) | 37 | (1.3) |
| Grade 4 | 3 | (0.4) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Activated partial thromboplastin time prolonged | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Alanine aminotransferase increased | 24 | (3.5) | 37 | (3.0) | 60 | (3.8) | 97 | (3.5) |
| Grade 1 | 18 | (2.6) | 24 | (1.9) | 41 | (2.6) | 65 | (2.3) |
| Grade 2 | 3 | (0.4) | 7 | (0.6) | 11 | (0.7) | 18 | (0.6) |
| Grade 3 | 3 | (0.4) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Amylase increased | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Aortic bruit | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aspartate aminotransferase | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Aspartate aminotransferase increased | 17 | (2.5) | 33 | (2.7) | 61 | (3.9) | 94 | (3.4) |
| Grade 1 | 8 | (1.2) | 19 | (1.5) | 46 | (2.9) | 65 | (2.3) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Aspartate aminotransferase increased | 17 | (2.5) | 33 | (2.7) | 61 | (3.9) | 94 | (3.4) |
| Grade 2 | 7 | (1.0) | 10 | (0.8) | 8 | (0.5) | 18 | (0.6) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Autoantibody positive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bilirubin conjugated increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood albumin decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood albumin increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood alkaline phosphatase decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood alkaline phosphatase increased | 11 | (1.6) | 17 | (1.4) | 20 | (1.3) | 37 | (1.3) |
| Grade 1 | 6 | (0.9) | 11 | (0.9) | 13 | (0.8) | 24 | (0.9) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Blood bicarbonate decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood bilirubin increased | 5 | (0.7) | 7 | (0.6) | 19 | (1.2) | 26 | (0.9) |
| Grade 1 | 4 | (0.6) | 5 | (0.4) | 11 | (0.7) | 16 | (0.6) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood calcium increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Blood chloride decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood cholesterol increased | 3 | (0.4) | 5 | (0.4) | 11 | (0.7) | 16 | (0.6) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood corticotrophin decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood corticotrophin increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood cortisol decreased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood creatine phosphokinase increased | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Blood creatine phosphokinase increased | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 4 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood creatinine increased | 13 | (1.9) | 17 | (1.4) | 18 | (1.1) | 35 | (1.3) |
| Grade 1 | 8 | (1.2) | 9 | (0.7) | 15 | (1.0) | 24 | (0.9) |
| Grade 2 | 5 | (0.7) | 8 | (0.6) | 3 | (0.2) | 11 | (0.4) |
| Blood glucose abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood glucose increased | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood lactate dehydrogenase increased | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood luteinising hormone decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood magnesium decreased | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood parathyroid hormone increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood phosphorus decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood prolactin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood testosterone decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood thyroid stimulating hormone decreased | 1 | (0.1) | 6 | (0.5) | 12 | (0.8) | 18 | (0.6) |
| Grade 1 | 1 | (0.1) | 6 | (0.5) | 10 | (0.6) | 16 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Blood thyroid stimulating hormone increased | 7 | (1.0) | 14 | (1.1) | 15 | (1.0) | 29 | (1.0) |
| Grade 1 | 5 | (0.7) | 11 | (0.9) | 12 | (0.8) | 23 | (0.8) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Blood triglycerides increased | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood urea increased | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Blood uric acid increased | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Body temperature increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Body temperature increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| C-reactive protein increased | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Electrocardiogram QT prolonged | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Electrocardiogram repolarisation abnormality | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eosinophil count increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Free thyroxine index increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gamma-glutamyltransferase increased | 5 | (0.7) | 6 | (0.5) | 12 | (0.8) | 18 | (0.6) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grip strength decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haematocrit decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haemoglobin decreased | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hepatic enzyme increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Immunoglobulins increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intraocular pressure decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lipase | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lipase increased | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Liver function test abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphocyte count decreased | 4 | (0.6) | 6 | (0.5) | 18 | (1.1) | 24 | (0.9) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 8 | (0.5) | 10 | (0.4) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 8 | (0.5) | 10 | (0.4) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Lymphocyte count decreased | 4 | (0.6) | 6 | (0.5) | 18 | (1.1) | 24 | (0.9) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutrophil count decreased | 2 | (0.3) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Neutrophil count increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Occult blood positive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Platelet count decreased | 4 | (0.6) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Platelet count increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Protein total decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Protein total increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Protein urine present | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Quality of life decreased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Thyroglobulin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine decreased | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine free decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thyroxine free increased | 5 | (0.7) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Grade 1 | 5 | (0.7) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Thyroxine increased | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Transaminases increased | 1 | (0.1) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Tri-iodothyronine decreased | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Tri-iodothyronine free decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Tri-iodothyronine free decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Tri-iodothyronine free increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tri-iodothyronine increased | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Weight decreased | 15 | (2.2) | 34 | (2.8) | 26 | (1.7) | 60 | (2.1) |
| Grade 1 | 8 | (1.2) | 19 | (1.5) | 18 | (1.1) | 37 | (1.3) |
| Grade 2 | 6 | (0.9) | 13 | (1.1) | 8 | (0.5) | 21 | (0.8) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Weight increased | 3 | (0.4) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Grade 1 | 2 | (0.3) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| White blood cell count decreased | 3 | (0.4) | 8 | (0.6) | 6 | (0.4) | 14 | (0.5) |
| Grade 1 | 1 | (0.1) | 6 | (0.5) | 4 | (0.3) | 10 | (0.4) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| White blood cell count increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Metabolism and nutrition disorders** | **119** | **(17.4)** | **190** | **(15.4)** | **198** | **(12.6)** | **388** | **(13.9)** |
| Grade 1 | 59 | (8.7) | 109 | (8.8) | 116 | (7.4) | 225 | (8.0) |
| Grade 2 | 39 | (5.7) | 57 | (4.6) | 55 | (3.5) | 112 | (4.0) |
| Grade 3 | 18 | (2.6) | 21 | (1.7) | 23 | (1.5) | 44 | (1.6) |
| Grade 4 | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Cell death | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Decreased appetite | 79 | (11.6) | 135 | (11.0) | 120 | (7.7) | 255 | (9.1) |
| Grade 1 | 45 | (6.6) | 88 | (7.1) | 83 | (5.3) | 171 | (6.1) |
| Grade 2 | 30 | (4.4) | 42 | (3.4) | 34 | (2.2) | 76 | (2.7) |
| Grade 3 | 4 | (0.6) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Dehydration | 2 | (0.3) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 2 | (0.3) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Diabetes mellitus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Electrolyte imbalance | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Failure to thrive | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fluid overload | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fluid retention | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gout | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperamylasaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypercalcaemia | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypercholesterolaemia | 4 | (0.6) | 6 | (0.5) | 3 | (0.2) | 9 | (0.3) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hyperglycaemia | 3 | (0.4) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Hyperkalaemia | 1 | (0.1) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Hyperlipidaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypermagnesaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypertriglyceridaemia | 10 | (1.5) | 12 | (1.0) | 12 | (0.8) | 24 | (0.9) |
| Grade 1 | 4 | (0.6) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 4 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hyperuricaemia | 2 | (0.3) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Hypoalbuminaemia | 6 | (0.9) | 7 | (0.6) | 4 | (0.3) | 11 | (0.4) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hypocalcaemia | 3 | (0.4) | 4 | (0.3) | 17 | (1.1) | 21 | (0.8) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 14 | (0.9) | 18 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Hypokalaemia | 4 | (0.6) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Hypokalaemia | 4 | (0.6) | 5 | (0.4) | 13 | (0.8) | 18 | (0.6) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 7 | (0.4) | 11 | (0.4) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hypomagnesaemia | 6 | (0.9) | 10 | (0.8) | 9 | (0.6) | 19 | (0.7) |
| Grade 1 | 6 | (0.9) | 10 | (0.8) | 6 | (0.4) | 16 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Hyponatraemia | 4 | (0.6) | 8 | (0.6) | 9 | (0.6) | 17 | (0.6) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 3 | (0.4) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Grade 4 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypophagia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypophosphataemia | 3 | (0.4) | 4 | (0.3) | 16 | (1.0) | 20 | (0.7) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Hypoproteinaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Increased appetite | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Insulin resistant diabetes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iron deficiency | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lactose intolerance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metabolic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Type 1 diabetes mellitus | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Type 2 diabetes mellitus | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vitamin B12 deficiency | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Musculoskeletal and connective tissue disorders** | **77** | **(11.3)** | **162** | **(13.1)** | **368** | **(23.5)** | **530** | **(18.9)** |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Musculoskeletal and connective tissue disorders** | **77** | **(11.3)** | **162** | **(13.1)** | **368** | **(23.5)** | **530** | **(18.9)** |
| Grade 1 | 45 | (6.6) | 103 | (8.4) | 236 | (15.1) | 339 | (12.1) |
| Grade 2 | 28 | (4.1) | 53 | (4.3) | 117 | (7.5) | 170 | (6.1) |
| Grade 3 | 4 | (0.6) | 6 | (0.5) | 15 | (1.0) | 21 | (0.8) |
| Ankylosing spondylitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Arthralgia | 32 | (4.7) | 81 | (6.6) | 200 | (12.8) | 281 | (10.0) |
| Grade 1 | 18 | (2.6) | 52 | (4.2) | 138 | (8.8) | 190 | (6.8) |
| Grade 2 | 12 | (1.8) | 25 | (2.0) | 59 | (3.8) | 84 | (3.0) |
| Grade 3 | 2 | (0.3) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Arthritis | 6 | (0.9) | 10 | (0.8) | 16 | (1.0) | 26 | (0.9) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 2 | 4 | (0.6) | 6 | (0.5) | 8 | (0.5) | 14 | (0.5) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Arthropathy | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Back pain | 9 | (1.3) | 15 | (1.2) | 32 | (2.0) | 47 | (1.7) |
| Grade 1 | 7 | (1.0) | 10 | (0.8) | 21 | (1.3) | 31 | (1.1) |
| Grade 2 | 1 | (0.1) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bone pain | 1 | (0.1) | 6 | (0.5) | 7 | (0.4) | 13 | (0.5) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bursitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chondrocalcinosis pyrophosphate | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fibromyalgia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Flank pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Groin pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Growing pains | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Joint effusion | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Joint effusion | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Joint range of motion decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Joint stiffness | 2 | (0.3) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 7 | (0.4) | 10 | (0.4) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Joint swelling | 2 | (0.3) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Kyphosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Limb discomfort | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mobility decreased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle atrophy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle necrosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscle spasms | 5 | (0.7) | 11 | (0.9) | 25 | (1.6) | 36 | (1.3) |
| Grade 1 | 5 | (0.7) | 11 | (0.9) | 23 | (1.5) | 34 | (1.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Muscle tightness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle twitching | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Muscular weakness | 2 | (0.3) | 2 | (0.2) | 20 | (1.3) | 22 | (0.8) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 11 | (0.7) | 12 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Musculoskeletal chest pain | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Musculoskeletal discomfort | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Musculoskeletal pain | 8 | (1.2) | 15 | (1.2) | 16 | (1.0) | 31 | (1.1) |
| Grade 1 | 7 | (1.0) | 11 | (0.9) | 12 | (0.8) | 23 | (0.8) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Musculoskeletal stiffness | 1 | (0.1) | 4 | (0.3) | 20 | (1.3) | 24 | (0.9) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 19 | (1.2) | 22 | (0.8) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Myalgia | 19 | (2.8) | 36 | (2.9) | 110 | (7.0) | 146 | (5.2) |
| Grade 1 | 11 | (1.6) | 25 | (2.0) | 84 | (5.4) | 109 | (3.9) |
| Grade 2 | 8 | (1.2) | 11 | (0.9) | 22 | (1.4) | 33 | (1.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Myopathy | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Myositis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Neck pain | 2 | (0.3) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 8 | (0.5) | 10 | (0.4) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Nodal osteoarthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Osteoarthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pain in extremity | 6 | (0.9) | 9 | (0.7) | 35 | (2.2) | 44 | (1.6) |
| Grade 1 | 6 | (0.9) | 6 | (0.5) | 25 | (1.6) | 31 | (1.1) |
| Grade 2 | 0 | (0.0) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pain in jaw | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Periarthritis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Plantar fasciitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Polyarthritis | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Polymyalgia rheumatica | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Rhabdomyolysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rheumatoid arthritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sjogren's syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Spinal pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Synovitis | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Temporomandibular joint syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tendon pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tendonitis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tenosynovitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Torticollis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **4** | **(0.6)** | **6** | **(0.5)** | **19** | **(1.2)** | **25** | **(0.9)** |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 16 | (1.0) | 18 | (0.6) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Acrochordon | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cancer pain | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Infected neoplasm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratoacanthoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malignant melanoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malignant neoplasm progression | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Melanocytic naevus | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Metastatic pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Neoplasm swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oncologic complication | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Paraneoplastic syndrome | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Seborrhoeic keratosis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Seborrhoeic keratosis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Skin papilloma | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Tumour pain | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| **Nervous system disorders** | **60** | **(8.8)** | **94** | **(7.6)** | **223** | **(14.2)** | **317** | **(11.3)** |
| Grade 1 | 42 | (6.2) | 66 | (5.4) | 171 | (10.9) | 237 | (8.5) |
| Grade 2 | 15 | (2.2) | 24 | (1.9) | 41 | (2.6) | 65 | (2.3) |
| Grade 3 | 3 | (0.4) | 4 | (0.3) | 10 | (0.6) | 14 | (0.5) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ageusia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Amnesia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Amnestic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ataxia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Balance disorder | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Brain oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Burning sensation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Carpal tunnel syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cerebrovascular accident | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cognitive disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Depressed level of consciousness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Disturbance in attention | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Dizziness | 11 | (1.6) | 16 | (1.3) | 30 | (1.9) | 46 | (1.6) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Dizziness | 11 | (1.6) | 16 | (1.3) | 30 | (1.9) | 46 | (1.6) |
| Grade 1 | 10 | (1.5) | 14 | (1.1) | 24 | (1.5) | 38 | (1.4) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Dysaesthesia | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Dysarthria | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dysgeusia | 11 | (1.6) | 14 | (1.1) | 31 | (2.0) | 45 | (1.6) |
| Grade 1 | 9 | (1.3) | 12 | (1.0) | 24 | (1.5) | 36 | (1.3) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Encephalopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Epilepsy | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Guillain-Barre syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Headache | 14 | (2.1) | 24 | (1.9) | 87 | (5.6) | 111 | (4.0) |
| Grade 1 | 13 | (1.9) | 21 | (1.7) | 72 | (4.6) | 93 | (3.3) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 13 | (0.8) | 16 | (0.6) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Horner's syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperaesthesia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hypersomnia | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hypoaesthesia | 3 | (0.4) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypogeusia | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypotonia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Judgement impaired | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lethargy | 3 | (0.4) | 9 | (0.7) | 11 | (0.7) | 20 | (0.7) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Loss of consciousness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Memory impairment | 0 | (0.0) | 0 | (0.0) | 10 | (0.6) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Meningitis noninfective | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myasthenic syndrome | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myelitis transverse | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neuralgia | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Neuropathy peripheral | 5 | (0.7) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| Grade 1 | 4 | (0.6) | 7 | (0.6) | 14 | (0.9) | 21 | (0.8) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Neurotoxicity | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Optic neuritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Paraesthesia | 6 | (0.9) | 10 | (0.8) | 14 | (0.9) | 24 | (0.9) |
| Grade 1 | 3 | (0.4) | 7 | (0.6) | 12 | (0.8) | 19 | (0.7) |
| Grade 2 | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Parosmia | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Partial seizures | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral motor neuropathy | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral sensory neuropathy | 6 | (0.9) | 7 | (0.6) | 5 | (0.3) | 12 | (0.4) |
| Grade 1 | 3 | (0.4) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Polyneuropathy | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Poor quality sleep | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Presyncope | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Presyncope | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Restless legs syndrome | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sciatica | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seizure | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sensory disturbance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Somnolence | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Syncope | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Toxic leukoencephalopathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Toxic neuropathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tremor | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| **Psychiatric disorders** | **11** | **(1.6)** | **14** | **(1.1)** | **52** | **(3.3)** | **66** | **(2.4)** |
| Grade 1 | 6 | (0.9) | 8 | (0.6) | 39 | (2.5) | 47 | (1.7) |
| Grade 2 | 3 | (0.4) | 4 | (0.3) | 11 | (0.7) | 15 | (0.5) |
| Grade 3 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Affective disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Agitation | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Anxiety | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Apathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Confusional state | 1 | (0.1) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Depression | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Disorientation | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Disorientation | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dysphoria | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hallucination | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Insomnia | 6 | (0.9) | 9 | (0.7) | 17 | (1.1) | 26 | (0.9) |
| Grade 1 | 4 | (0.6) | 6 | (0.5) | 13 | (0.8) | 19 | (0.7) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Irritability | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Libido decreased | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Middle insomnia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mood altered | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Personality change | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Phobia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Restlessness | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sleep disorder | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Trance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Renal and urinary disorders** | **11** | **(1.6)** | **18** | **(1.5)** | **25** | **(1.6)** | **43** | **(1.5)** |
| Grade 1 | 4 | (0.6) | 8 | (0.6) | 13 | (0.8) | 21 | (0.8) |
| Grade 2 | 5 | (0.7) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Grade 3 | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Acute kidney injury | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Chromaturia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chronic kidney disease | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cystitis noninfective | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dysuria | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haematuria | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Micturition urgency | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nocturia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pollakiuria | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Proteinuria | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Renal failure | 2 | (0.3) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Renal impairment | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Tubulointerstitial nephritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary incontinence | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urinary retention | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urine odour abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Reproductive system and breast disorders** | **4** | **(0.6)** | **6** | **(0.5)** | **20** | **(1.3)** | **26** | **(0.9)** |
| Grade 1 | 3 | (0.4) | 5 | (0.4) | 19 | (1.2) | 24 | (0.9) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Amenorrhoea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Balanoposthitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Breast pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breast tenderness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dysmenorrhoea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erectile dysfunction | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Genital rash | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gynaecomastia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Haematospermia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Menorrhagia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Nipple pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nipple swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pelvic pain | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Pruritus genital | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Scrotal erythema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal dryness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vulvovaginal pruritus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Respiratory, thoracic and mediastinal disorders** | **74** | **(10.9)** | **142** | **(11.5)** | **209** | **(13.3)** | **351** | **(12.5)** |
| Grade 1 | 29 | (4.3) | 56 | (4.5) | 136 | (8.7) | 192 | (6.9) |
| Grade 2 | 28 | (4.1) | 55 | (4.5) | 52 | (3.3) | 107 | (3.8) |
| Grade 3 | 10 | (1.5) | 19 | (1.5) | 20 | (1.3) | 39 | (1.4) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Respiratory, thoracic and mediastinal disorders** | **74** | **(10.9)** | **142** | **(11.5)** | **209** | **(13.3)** | **351** | **(12.5)** |
| Grade 4 | 4 | (0.6) | 7 | (0.6) | 1 | (0.1) | 8 | (0.3) |
| Grade 5 | 3 | (0.4) | 5 | (0.4) | 0 | (0.0) | 5 | (0.2) |
| Asthma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchial hyperreactivity | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Bronchospasm | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Chronic obstructive pulmonary disease | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cough | 11 | (1.6) | 24 | (1.9) | 88 | (5.6) | 112 | (4.0) |
| Grade 1 | 7 | (1.0) | 17 | (1.4) | 77 | (4.9) | 94 | (3.4) |
| Grade 2 | 4 | (0.6) | 7 | (0.6) | 10 | (0.6) | 17 | (0.6) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dysphonia | 2 | (0.3) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dyspnoea | 21 | (3.1) | 43 | (3.5) | 66 | (4.2) | 109 | (3.9) |
| Grade 1 | 10 | (1.5) | 22 | (1.8) | 44 | (2.8) | 66 | (2.4) |
| Grade 2 | 7 | (1.0) | 16 | (1.3) | 15 | (1.0) | 31 | (1.1) |
| Grade 3 | 4 | (0.6) | 5 | (0.4) | 6 | (0.4) | 11 | (0.4) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dyspnoea exertional | 2 | (0.3) | 7 | (0.6) | 13 | (0.8) | 20 | (0.7) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Grade 2 | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Epistaxis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Haemoptysis | 3 | (0.4) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Hiccups | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypoxia | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Interstitial lung disease | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Interstitial lung disease | 3 | (0.4) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Laryngeal discomfort | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Laryngeal inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lung disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasal congestion | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Nasal dryness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nasal mucosal disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oropharyngeal pain | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Painful respiration | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pleural effusion | 5 | (0.7) | 9 | (0.7) | 2 | (0.1) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 3 | (0.4) | 5 | (0.4) | 1 | (0.1) | 6 | (0.2) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pleuritic pain | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumonitis | 26 | (3.8) | 47 | (3.8) | 33 | (2.1) | 80 | (2.9) |
| Grade 1 | 4 | (0.6) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Grade 2 | 10 | (1.5) | 18 | (1.5) | 15 | (1.0) | 33 | (1.2) |
| Grade 3 | 5 | (0.7) | 12 | (1.0) | 10 | (0.6) | 22 | (0.8) |
| Grade 4 | 4 | (0.6) | 7 | (0.6) | 0 | (0.0) | 7 | (0.3) |
| Grade 5 | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Pneumothorax | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Productive cough | 0 | (0.0) | 7 | (0.6) | 6 | (0.4) | 13 | (0.5) |
| Grade 1 | 0 | (0.0) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Pulmonary congestion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pulmonary embolism | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pulmonary oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Respiration abnormal | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory failure | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 5 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory tract congestion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rhinitis allergic | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Rhinorrhoea | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Sinus congestion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sneezing | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Sputum discoloured | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tachypnoea | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Throat irritation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Throat tightness | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper respiratory tract congestion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper-airway cough syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Wheezing | 0 | (0.0) | 0 | (0.0) | 9 | (0.6) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 8 | (0.5) | 8 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Skin and subcutaneous tissue disorders** | **148** | **(21.7)** | **282** | **(22.9)** | **738** | **(47.1)** | **1,020** | **(36.4)** |
| Grade 1 | 97 | (14.2) | 202 | (16.4) | 586 | (37.4) | 788 | (28.2) |
| Grade 2 | 45 | (6.6) | 69 | (5.6) | 134 | (8.6) | 203 | (7.3) |
| Grade 3 | 6 | (0.9) | 11 | (0.9) | 18 | (1.1) | 29 | (1.0) |



C Confidential

## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Acne | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Actinic keratosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Alopecia | 5 | (0.7) | 8 | (0.6) | 16 | (1.0) | 24 | (0.9) |
| Grade 1 | 5 | (0.7) | 8 | (0.6) | 16 | (1.0) | 24 | (0.9) |
| Angioedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blister | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dermatitis | 2 | (0.3) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dermatitis acneiform | 2 | (0.3) | 15 | (1.2) | 13 | (0.8) | 28 | (1.0) |
| Grade 1 | 1 | (0.1) | 13 | (1.1) | 11 | (0.7) | 24 | (0.9) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Dermatitis allergic | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dermatitis atopic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatitis bullous | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dermatitis contact | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dermatitis exfoliative | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dermatitis psoriasiform | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Drug eruption | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dry skin | 18 | (2.6) | 37 | (3.0) | 53 | (3.4) | 90 | (3.2) |
| Grade 1 | 17 | (2.5) | 34 | (2.8) | 47 | (3.0) | 81 | (2.9) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 6 | (0.4) | 9 | (0.3) |
| Eczema | 4 | (0.6) | 5 | (0.4) | 25 | (1.6) | 30 | (1.1) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 21 | (1.3) | 25 | (0.9) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Eczema asteatotic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eczema nummular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erythema | 3 | (0.4) | 6 | (0.5) | 40 | (2.6) | 46 | (1.6) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Erythema | 3 | (0.4) | 6 | (0.5) | 40 | (2.6) | 46 | (1.6) |
| Grade 1 | 3 | (0.4) | 6 | (0.5) | 36 | (2.3) | 42 | (1.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Erythema multiforme | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Erythema nodosum | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Exfoliative rash | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Generalised erythema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Granuloma skin | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hair colour changes | 0 | (0.0) | 0 | (0.0) | 16 | (1.0) | 16 | (0.6) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 15 | (1.0) | 15 | (0.5) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hair growth abnormal | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Hair texture abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperhidrosis | 1 | (0.1) | 4 | (0.3) | 14 | (0.9) | 18 | (0.6) |
| Grade 1 | 1 | (0.1) | 4 | (0.3) | 14 | (0.9) | 18 | (0.6) |
| Hyperkeratosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypertrichosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ichthyosis acquired | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Keratosis pilaris | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Lichen planus | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lichen sclerosus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lichenoid keratosis | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Linear IgA disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Macule | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Macule | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Madarosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mucocutaneous rash | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail discolouration | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Nail disorder | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Nail dystrophy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail growth abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail ridging | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nail toxicity | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutrophilic dermatosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Night sweats | 4 | (0.6) | 5 | (0.4) | 30 | (1.9) | 35 | (1.3) |
| Grade 1 | 3 | (0.4) | 4 | (0.3) | 28 | (1.8) | 32 | (1.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Onychalgia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Onychoclasis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Onycholysis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Onychomadesis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pain of skin | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Palmar-plantar erythrodysaesthesia syndrome | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Panniculitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Papule | 0 | (0.0) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Parapsoriasis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Pemphigoid | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Petechiae | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Photosensitivity reaction | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Pigmentation disorder | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Prurigo | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pruritus | 57 | (8.4) | 116 | (9.4) | 351 | (22.4) | 467 | (16.7) |
| Grade 1 | 40 | (5.9) | 90 | (7.3) | 305 | (19.5) | 395 | (14.1) |
| Grade 2 | 17 | (2.5) | 26 | (2.1) | 44 | (2.8) | 70 | (2.5) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pruritus allergic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pruritus generalised | 2 | (0.3) | 3 | (0.2) | 16 | (1.0) | 19 | (0.7) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 15 | (1.0) | 18 | (0.6) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Psoriasis | 4 | (0.6) | 6 | (0.5) | 6 | (0.4) | 12 | (0.4) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Purpura | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pustular psoriasis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rash | 73 | (10.7) | 123 | (10.0) | 263 | (16.8) | 386 | (13.8) |
| Grade 1 | 53 | (7.8) | 95 | (7.7) | 223 | (14.2) | 318 | (11.4) |
| Grade 2 | 18 | (2.6) | 24 | (1.9) | 38 | (2.4) | 62 | (2.2) |
| Grade 3 | 2 | (0.3) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Rash erythematous | 0 | (0.0) | 1 | (0.1) | 11 | (0.7) | 12 | (0.4) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rash follicular | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rash generalised | 0 | (0.0) | 2 | (0.2) | 14 | (0.9) | 16 | (0.6) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Rash macular | 2 | (0.3) | 6 | (0.5) | 9 | (0.6) | 15 | (0.5) |
| Grade 1 | 2 | (0.3) | 5 | (0.4) | 9 | (0.6) | 14 | (0.5) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rash maculo-papular | 9 | (1.3) | 17 | (1.4) | 59 | (3.8) | 76 | (2.7) |
| Grade 1 | 6 | (0.9) | 12 | (1.0) | 37 | (2.4) | 49 | (1.8) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 17 | (1.1) | 20 | (0.7) |
| Grade 3 | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Rash papular | 0 | (0.0) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Grade 1 | 0 | (0.0) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Rash pruritic | 5 | (0.7) | 8 | (0.6) | 18 | (1.1) | 26 | (0.9) |
| Grade 1 | 4 | (0.6) | 5 | (0.4) | 14 | (0.9) | 19 | (0.7) |
| Grade 2 | 1 | (0.1) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rash vesicular | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rosacea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Scab | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sebaceous gland disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seborrhoeic dermatitis | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Grade 1 | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin burning sensation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin depigmentation | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Skin discolouration | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Skin disorder | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin exfoliation | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin fissures | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin hyperpigmentation | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Skin hypopigmentation | 0 | (0.0) | 1 | (0.1) | 29 | (1.9) | 30 | (1.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 25 | (1.6) | 26 | (0.9) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Skin irritation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin lesion | 2 | (0.3) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 9 | (0.6) | 11 | (0.4) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin mass | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Skin plaque | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin reaction | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin ulcer | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Solar dermatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stevens-Johnson syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Swelling face | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Toxic skin eruption | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Transient acantholytic dermatosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urticaria | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urticaria papular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vitiligo | 1 | (0.1) | 1 | (0.1) | 158 | (10.1) | 159 | (5.7) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 135 | (8.6) | 136 | (4.9) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 23 | (1.5) | 23 | (0.8) |
| Xanthelasma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Xeroderma | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| **Vascular disorders** | **16** | **(2.3)** | **33** | **(2.7)** | **48** | **(3.1)** | **81** | **(2.9)** |
| Grade 1 | 7 | (1.0) | 16 | (1.3) | 37 | (2.4) | 53 | (1.9) |
| Grade 2 | 5 | (0.7) | 10 | (0.8) | 6 | (0.4) | 16 | (0.6) |
| Grade 3 | 4 | (0.6) | 7 | (0.6) | 4 | (0.3) | 11 | (0.4) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade (Incidence >0% in One or More Treatment Groups) PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475 (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Arterial thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Deep vein thrombosis | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 2 | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Embolism | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Flushing | 3 | (0.4) | 4 | (0.3) | 9 | (0.6) | 13 | (0.5) |
| Grade 1 | 2 | (0.3) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hot flush | 1 | (0.1) | 5 | (0.4) | 17 | (1.1) | 22 | (0.8) |
| Grade 1 | 1 | (0.1) | 5 | (0.4) | 17 | (1.1) | 22 | (0.8) |
| Hyperaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypertension | 5 | (0.7) | 8 | (0.6) | 5 | (0.3) | 13 | (0.5) |
| Grade 1 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Grade 3 | 2 | (0.3) | 4 | (0.3) | 3 | (0.2) | 7 | (0.3) |
| Hypotension | 3 | (0.4) | 3 | (0.2) | 3 | (0.2) | 6 | (0.2) |
| Grade 1 | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Grade 2 | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Intermittent claudication | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Jugular vein thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lymphoedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Orthostatic hypotension | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pallor | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral coldness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peripheral ischaemia | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 3 | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 4 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Phlebitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Prehypertension | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Drug-Related Adverse Events by Maximum Toxicity Grade
## (Incidence >0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Prehypertension | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Raynaud's phenomenon | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Superior vena cava syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Thrombophlebitis superficial | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Varicophlebitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Vasculitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Grade 1 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 3 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vasospasm | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Grade 1 | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Venous thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Grade 2 | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |

Every subject is counted a single time for each applicable specific adverse event. A subject with multiple adverse events within a system organ class is counted a single time for that system organ class.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns is greater than or equal to the incidence specified in the report title, after rounding.

Only the highest reported grade of a given adverse event is counted for the individual subject.

Grades are based on NCI CTCAE version 4.0.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted]).

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).



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付録 2.7.4- 34　　Grade 3 以上の有害事象（いずれかの投与群で発現割合 0%超）

001 試験＋002 試験＋006 試験＋010 試験

MK-3475 を投与された悪性黒色腫及び非小細胞肺癌患者（安全性解析対象集団）

Subjects With Grade 3-5 Adverse Events
(Incidence > 0% in One or More Treatment Groups)
PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
(APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| Subjects in population | 682 | | 1,232 | | 1,567 | | 2,799 | |
| with one or more adverse events | 314 | (46.0) | 568 | (46.1) | 705 | (45.0) | 1,273 | (45.5) |
| with no adverse events | 368 | (54.0) | 664 | (53.9) | 862 | (55.0) | 1,526 | (54.5) |
| **Blood and lymphatic system disorders** | **26** | **(3.8)** | **43** | **(3.5)** | **80** | **(5.1)** | **123** | **(4.4)** |
| Anaemia | 16 | (2.3) | 27 | (2.2) | 63 | (4.0) | 90 | (3.2) |
| Autoimmune haemolytic anaemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Disseminated intravascular coagulation | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Febrile neutropenia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Haemolytic anaemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Immune thrombocytopenic purpura | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Leukocytosis | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Leukopenia | 1 | (0.1) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Lymphadenopathy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lymphopenia | 1 | (0.1) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Microcytic anaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neutropenia | 0 | (0.0) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Normochromic normocytic anaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pancytopenia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thrombocytopenia | 3 | (0.4) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| **Cardiac disorders** | **23** | **(3.4)** | **49** | **(4.0)** | **35** | **(2.2)** | **84** | **(3.0)** |
| Acute coronary syndrome | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Acute myocardial infarction | 2 | (0.3) | 5 | (0.4) | 3 | (0.2) | 8 | (0.3) |
| Arrhythmia supraventricular | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Atrial fibrillation | 1 | (0.1) | 5 | (0.4) | 8 | (0.5) | 13 | (0.5) |
| Atrial flutter | 0 | (0.0) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Atrial thrombosis | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Atrioventricular block complete | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bradycardia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Cardiac disorders** | **23** | **(3.4)** | **49** | **(4.0)** | **35** | **(2.2)** | **84** | **(3.0)** |
| Cardiac arrest | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Cardiac failure | 2 | (0.3) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Cardiac failure congestive | 0 | (0.0) | 2 | (0.2) | 7 | (0.4) | 9 | (0.3) |
| Cardiac tamponade | 1 | (0.1) | 6 | (0.5) | 0 | (0.0) | 6 | (0.2) |
| Cardiac ventricular disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cardio-respiratory arrest | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Cardiomyopathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cardiopulmonary failure | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Congestive cardiomyopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Coronary artery disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myocardial infarction | 2 | (0.3) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Palpitations | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pericardial effusion | 7 | (1.0) | 10 | (0.8) | 4 | (0.3) | 14 | (0.5) |
| Pericarditis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pericarditis constrictive | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Right ventricular failure | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sinus bradycardia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Sinus tachycardia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Supraventricular tachycardia | 1 | (0.1) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Tachycardia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Congenital, familial and genetic disorders** | **3** | **(0.4)** | **3** | **(0.2)** | **0** | **(0.0)** | **3** | **(0.1)** |
| Pyloric stenosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tracheo-oesophageal fistula | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| **Ear and labyrinth disorders** | **1** | **(0.1)** | **1** | **(0.1)** | **2** | **(0.1)** | **3** | **(0.1)** |
| Deafness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tinnitus | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vertigo | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vertigo positional | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Endocrine disorders** | **4** | **(0.6)** | **8** | **(0.6)** | **18** | **(1.1)** | **26** | **(0.9)** |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Endocrine disorders** | **4** | **(0.6)** | **8** | **(0.6)** | **18** | **(1.1)** | **26** | **(0.9)** |
| Adrenal haemorrhage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Adrenal insufficiency | 1 | (0.1) | 2 | (0.2) | 6 | (0.4) | 8 | (0.3) |
| Adrenocortical insufficiency acute | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperthyroidism | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Hypophysitis | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Hypopituitarism | 2 | (0.3) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Hypothyroidism | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Secondary adrenocortical insufficiency | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Eye disorders** | **3** | **(0.4)** | **3** | **(0.2)** | **8** | **(0.5)** | **11** | **(0.4)** |
| Cataract | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Entropion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye movement disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eye pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Eyelid function disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Glaucoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Iritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Retinal detachment | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Gastrointestinal disorders** | **42** | **(6.2)** | **76** | **(6.2)** | **156** | **(10.0)** | **232** | **(8.3)** |
| Abdominal distension | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal mass | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Abdominal pain | 3 | (0.4) | 8 | (0.6) | 19 | (1.2) | 27 | (1.0) |
| Abdominal pain lower | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Abdominal pain upper | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Anal fistula | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ascites | 2 | (0.3) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Autoimmune pancreatitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Colitis | 4 | (0.6) | 9 | (0.7) | 23 | (1.5) | 32 | (1.1) |
| Constipation | 4 | (0.6) | 6 | (0.5) | 6 | (0.4) | 12 | (0.4) |
| Dental caries | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Diarrhoea | 3 | (0.4) | 7 | (0.6) | 29 | (1.9) | 36 | (1.3) |
| Diverticulitis intestinal haemorrhagic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Diverticulum | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Gastrointestinal disorders** | **42** | **(6.2)** | **76** | **(6.2)** | **156** | **(10.0)** | **232** | **(8.3)** |
| Dry mouth | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Duodenal ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Dysphagia | 5 | (0.7) | 5 | (0.4) | 2 | (0.1) | 7 | (0.3) |
| Enterocolitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Faecaloma | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastric disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastric haemorrhage | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastric perforation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastric ulcer haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastritis | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Gastrointestinal disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastrointestinal haemorrhage | 0 | (0.0) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Gastrointestinal pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Gastrointestinal perforation | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haematemesis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haematochezia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Ileus | 1 | (0.1) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Impaired gastric emptying | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Inguinal hernia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intestinal obstruction | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Intestinal perforation | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Intussusception | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Large intestinal obstruction | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Large intestinal ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Large intestine perforation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malabsorption | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Melaena | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Nausea | 9 | (1.3) | 14 | (1.1) | 19 | (1.2) | 33 | (1.2) |
| Obstruction gastric | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Odynophagia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Oesophageal obstruction | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Oesophageal stenosis | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |


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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Gastrointestinal disorders** | **42** | **(6.2)** | **76** | **(6.2)** | **156** | **(10.0)** | **232** | **(8.3)** |
| Oesophagitis | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Oral pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pancreatitis | 1 | (0.1) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Pancreatitis acute | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Peptic ulcer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rectal haemorrhage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Small intestinal obstruction | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Small intestinal perforation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stomatitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Stomatitis necrotising | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Upper gastrointestinal haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Vomiting | 6 | (0.9) | 9 | (0.7) | 23 | (1.5) | 32 | (1.1) |
| **General disorders and administration site conditions** | **55** | **(8.1)** | **104** | **(8.4)** | **110** | **(7.0)** | **214** | **(7.6)** |
| Adverse drug reaction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Asthenia | 9 | (1.3) | 16 | (1.3) | 18 | (1.1) | 34 | (1.2) |
| Axillary pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Chest pain | 6 | (0.9) | 9 | (0.7) | 4 | (0.3) | 13 | (0.5) |
| Crepitations | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cyst | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Death | 6 | (0.9) | 8 | (0.6) | 9 | (0.6) | 17 | (0.6) |
| Device dislocation | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Drug withdrawal syndrome | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Fatigue | 21 | (3.1) | 37 | (3.0) | 32 | (2.0) | 69 | (2.5) |
| Gait disturbance | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| General physical health deterioration | 6 | (0.9) | 9 | (0.7) | 15 | (1.0) | 24 | (0.9) |
| Generalised oedema | 0 | (0.0) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Impaired healing | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Influenza like illness | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Local swelling | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Localised oedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malaise | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **General disorders and administration site conditions** | **55** | **(8.1)** | **104** | **(8.4)** | **110** | **(7.0)** | **214** | **(7.6)** |
| Mucosal inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Multi-organ failure | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Non-cardiac chest pain | 1 | (0.1) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Oedema | 0 | (0.0) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Oedema peripheral | 1 | (0.1) | 1 | (0.1) | 10 | (0.6) | 11 | (0.4) |
| Pain | 4 | (0.6) | 15 | (1.2) | 8 | (0.5) | 23 | (0.8) |
| Pyrexia | 5 | (0.7) | 8 | (0.6) | 5 | (0.3) | 13 | (0.5) |
| Systemic inflammatory response syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Thrombosis in device | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Hepatobiliary disorders** | **7** | **(1.0)** | **9** | **(0.7)** | **34** | **(2.2)** | **43** | **(1.5)** |
| Autoimmune hepatitis | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Bile duct obstruction | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Bile duct stone | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Biliary dilatation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cholecystitis | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Cholecystitis acute | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cholestasis | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Drug-induced liver injury | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Hepatic failure | 1 | (0.1) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Hepatic function abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatitis | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Hepatocellular injury | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hepatomegaly | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperbilirubinaemia | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Jaundice | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Jaundice cholestatic | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Liver disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Portal hypertension | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Immune system disorders** | **2** | **(0.3)** | **3** | **(0.2)** | **4** | **(0.3)** | **7** | **(0.3)** |
| Anaphylactic reaction | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Anaphylactoid reaction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Drug hypersensitivity | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypersensitivity | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Immune system disorders** | **2** | **(0.3)** | **3** | **(0.2)** | **4** | **(0.3)** | **7** | **(0.3)** |
| Serum sickness | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Infections and infestations** | **71** | **(10.4)** | **108** | **(8.8)** | **112** | **(7.1)** | **220** | **(7.9)** |
| Appendicitis perforated | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bacillus bacteraemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bacterial sepsis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Bronchitis | 1 | (0.1) | 3 | (0.2) | 5 | (0.3) | 8 | (0.3) |
| Catheter site infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cellulitis | 0 | (0.0) | 0 | (0.0) | 14 | (0.9) | 14 | (0.5) |
| Cellulitis streptococcal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clostridium difficile colitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clostridium difficile infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Conjunctivitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Device related infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Device related sepsis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Diverticulitis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Encephalitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Endocarditis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Enterococcal infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Enterocolitis infectious | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erysipelas | 0 | (0.0) | 0 | (0.0) | 6 | (0.4) | 6 | (0.2) |
| Escherichia bacteraemia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastroenteritis | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Gastroenteritis viral | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastrointestinal infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Genital infection fungal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Herpes simplex encephalitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Herpes zoster | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infected cyst | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Infection | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Infectious pleural effusion | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Infections and infestations** | **71** | **(10.4)** | **108** | **(8.8)** | **112** | **(7.1)** | **220** | **(7.9)** |
| Infective exacerbation of chronic obstructive airways disease | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Influenza | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Klebsiella infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Listeriosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Liver abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lobar pneumonia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Localised infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lower respiratory tract infection | 1 | (0.1) | 5 | (0.4) | 0 | (0.0) | 5 | (0.2) |
| Lung infection | 4 | (0.6) | 6 | (0.5) | 3 | (0.2) | 9 | (0.3) |
| Lyme disease | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Mastitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Meningitis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Meningitis listeria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Nosocomial infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Oesophageal candidiasis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Osteomyelitis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pelvic abscess | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Peritonitis bacterial | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pharyngitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pleural infection | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumocystis jirovecii pneumonia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia | 36 | (5.3) | 50 | (4.1) | 24 | (1.5) | 74 | (2.6) |
| Pneumonia bacterial | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pneumonia pneumococcal | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pseudomonas infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pulmonary sepsis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pyelonephritis acute | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pyopneumothorax | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rash pustular | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory tract infection | 5 | (0.7) | 6 | (0.5) | 1 | (0.1) | 7 | (0.3) |
| Respiratory tract infection viral | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Infections and infestations** | **71** | **(10.4)** | **108** | **(8.8)** | **112** | **(7.1)** | **220** | **(7.9)** |
| Sepsis | 0 | (0.0) | 2 | (0.2) | 11 | (0.7) | 13 | (0.5) |
| Septic shock | 1 | (0.1) | 2 | (0.2) | 3 | (0.2) | 5 | (0.2) |
| Sinusitis | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Skin infection | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Soft tissue infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Staphylococcal infection | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tooth abscess | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tracheitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Upper respiratory tract infection | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Urinary tract infection | 1 | (0.1) | 2 | (0.2) | 12 | (0.8) | 14 | (0.5) |
| Urosepsis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Viral infection | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Viral upper respiratory tract infection | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Wound infection | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Wound sepsis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Injury, poisoning and procedural complications** | **10** | **(1.5)** | **14** | **(1.1)** | **24** | **(1.5)** | **38** | **(1.4)** |
| Ankle fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Clavicle fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Contusion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Facial bones fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fall | 2 | (0.3) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Femoral neck fracture | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Femur fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fracture displacement | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Fractured sacrum | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hip fracture | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Humerus fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Incisional hernia, obstructive | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Joint injury | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lower limb fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumonitis chemical | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Procedural pain | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Radiation necrosis | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |


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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Injury, poisoning and procedural complications** | **10** | **(1.5)** | **14** | **(1.1)** | **24** | **(1.5)** | **38** | **(1.4)** |
| Radiation pneumonitis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Rib fracture | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Spinal compression fracture | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Spinal fracture | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Traumatic intracranial haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Upper limb fracture | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vascular access complication | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Wound decomposition | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Wound haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Investigations** | **32** | **(4.7)** | **54** | **(4.4)** | **76** | **(4.9)** | **130** | **(4.6)** |
| Alanine aminotransferase increased | 5 | (0.7) | 9 | (0.7) | 16 | (1.0) | 25 | (0.9) |
| Amylase increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Anion gap increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aspartate aminotransferase increased | 5 | (0.7) | 9 | (0.7) | 15 | (1.0) | 24 | (0.9) |
| Aspiration bronchial | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bilirubin conjugated increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood albumin decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood albumin increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood alkaline phosphatase increased | 6 | (0.9) | 9 | (0.7) | 7 | (0.4) | 16 | (0.6) |
| Blood bicarbonate decreased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood bilirubin increased | 1 | (0.1) | 5 | (0.4) | 9 | (0.6) | 14 | (0.5) |
| Blood cholesterol increased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Investigations** | **32** | **(4.7)** | **54** | **(4.4)** | **76** | **(4.9)** | **130** | **(4.6)** |
| Blood corticotrophin decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood creatine phosphokinase increased | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Blood creatinine increased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Blood glucose increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood lactate dehydrogenase increased | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Blood lactic acid increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood pressure increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Blood prolactin increased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Blood triglycerides increased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Blood uric acid increased | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cortisol free urine decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrocardiogram change | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gamma-glutamyltransferase increased | 6 | (0.9) | 8 | (0.6) | 9 | (0.6) | 17 | (0.6) |
| Haemoglobin decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hepatic enzyme increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| International normalised ratio increased | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Intraocular pressure decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lipase increased | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Liver function test abnormal | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Investigations** | **32** | **(4.7)** | **54** | **(4.4)** | **76** | **(4.9)** | **130** | **(4.6)** |
| Lymphocyte count decreased | 3 | (0.4) | 4 | (0.3) | 8 | (0.5) | 12 | (0.4) |
| Neutrophil count decreased | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Neutrophil count increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Occult blood | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Platelet count decreased | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Transaminases increased | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Troponin I increased | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urine output decreased | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Weight decreased | 3 | (0.4) | 4 | (0.3) | 4 | (0.3) | 8 | (0.3) |
| Weight increased | 0 | (0.0) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| White blood cell count decreased | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| **Metabolism and nutrition disorders** | **58** | **(8.5)** | **97** | **(7.9)** | **136** | **(8.7)** | **233** | **(8.3)** |
| Cachexia | 0 | (0.0) | 1 | (0.1) | 3 | (0.2) | 4 | (0.1) |
| Cell death | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Decreased appetite | 10 | (1.5) | 15 | (1.2) | 11 | (0.7) | 26 | (0.9) |
| Dehydration | 5 | (0.7) | 9 | (0.7) | 19 | (1.2) | 28 | (1.0) |
| Diabetes mellitus | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Diabetic ketoacidosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Diabetic metabolic decompensation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Electrolyte imbalance | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Failure to thrive | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Gout | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hyperamylasaemia | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypercalcaemia | 7 | (1.0) | 11 | (0.9) | 4 | (0.3) | 15 | (0.5) |
| Hypercholesterolaemia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperglycaemia | 10 | (1.5) | 12 | (1.0) | 17 | (1.1) | 29 | (1.0) |
| Hyperkalaemia | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Hypertriglyceridaemia | 4 | (0.6) | 5 | (0.4) | 11 | (0.7) | 16 | (0.6) |
| Hyperuricaemia | 0 | (0.0) | 1 | (0.1) | 5 | (0.3) | 6 | (0.2) |
| Hypoalbuminaemia | 1 | (0.1) | 5 | (0.4) | 10 | (0.6) | 15 | (0.5) |
| Hypocalcaemia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Hypoglycaemia | 0 | (0.0) | 1 | (0.1) | 4 | (0.3) | 5 | (0.2) |
| Hypokalaemia | 7 | (1.0) | 11 | (0.9) | 14 | (0.9) | 25 | (0.9) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Metabolism and nutrition disorders** | **58** | **(8.5)** | **97** | **(7.9)** | **136** | **(8.7)** | **233** | **(8.3)** |
| Hyponatraemia | 13 | (1.9) | 24 | (1.9) | 38 | (2.4) | 62 | (2.2) |
| Hypophosphataemia | 4 | (0.6) | 6 | (0.5) | 8 | (0.5) | 14 | (0.5) |
| Insulin resistant diabetes | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lactic acidosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Malnutrition | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metabolic acidosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Metabolic disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tumour lysis syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Type 1 diabetes mellitus | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| **Musculoskeletal and connective tissue disorders** | **32** | **(4.7)** | **56** | **(4.5)** | **70** | **(4.5)** | **126** | **(4.5)** |
| Arthralgia | 7 | (1.0) | 11 | (0.9) | 6 | (0.4) | 17 | (0.6) |
| Arthritis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Back pain | 10 | (1.5) | 20 | (1.6) | 18 | (1.1) | 38 | (1.4) |
| Bone pain | 4 | (0.6) | 7 | (0.6) | 1 | (0.1) | 8 | (0.3) |
| Costochondritis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Flank pain | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Groin pain | 0 | (0.0) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Intervertebral disc protrusion | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Joint range of motion decreased | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lower extremity mass | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Muscle haemorrhage | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Muscular weakness | 0 | (0.0) | 1 | (0.1) | 9 | (0.6) | 10 | (0.4) |
| Musculoskeletal chest pain | 1 | (0.1) | 6 | (0.5) | 2 | (0.1) | 8 | (0.3) |
| Musculoskeletal pain | 6 | (0.9) | 8 | (0.6) | 8 | (0.5) | 16 | (0.6) |
| Myalgia | 1 | (0.1) | 1 | (0.1) | 7 | (0.4) | 8 | (0.3) |
| Neck pain | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Osteolysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Osteoporotic fracture | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pain in extremity | 4 | (0.6) | 5 | (0.4) | 7 | (0.4) | 12 | (0.4) |
| Pathological fracture | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Rhabdomyolysis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Sjogren's syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Musculoskeletal and connective tissue disorders** | **32** | **(4.7)** | **56** | **(4.5)** | **70** | **(4.5)** | **126** | **(4.5)** |
| Spinal column stenosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Spinal pain | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Spondylolisthesis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Synovitis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **17** | **(2.5)** | **28** | **(2.3)** | **51** | **(3.3)** | **79** | **(2.8)** |
| Abdominal neoplasm | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Adenocarcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Adenocarcinoma gastric | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Basal cell carcinoma | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Basosquamous carcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Breast cancer | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Cancer pain | 2 | (0.3) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Colon cancer metastatic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Gastric cancer | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Gastrointestinal carcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Intracranial tumour haemorrhage | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Invasive ductal breast carcinoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Leiomyosarcoma | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lung neoplasm malignant | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lymphangiosis carcinomatosa | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Malignant melanoma | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Malignant neoplasm progression | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Malignant pleural effusion | 2 | (0.3) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Metastases to bone | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Metastases to central nervous system | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Neoplasms benign, malignant and unspecified (incl cysts and polyps)** | **17** | **(2.5)** | **28** | **(2.3)** | **51** | **(3.3)** | **79** | **(2.8)** |
| Metastases to large intestine | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastases to meninges | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Metastatic malignant melanoma | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Metastatic pain | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Oncologic complication | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Papillary thyroid cancer | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Paraneoplastic syndrome | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pericardial effusion malignant | 0 | (0.0) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Prostate cancer | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Squamous cell carcinoma | 0 | (0.0) | 0 | (0.0) | 7 | (0.4) | 7 | (0.3) |
| Tumour haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Tumour pain | 5 | (0.7) | 10 | (0.8) | 7 | (0.4) | 17 | (0.6) |
| **Nervous system disorders** | **23** | **(3.4)** | **34** | **(2.8)** | **74** | **(4.7)** | **108** | **(3.9)** |
| Amnesia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aphasia | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Ataxia | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Brain oedema | 1 | (0.1) | 2 | (0.2) | 4 | (0.3) | 6 | (0.2) |
| Cerebral haemorrhage | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Cerebrovascular accident | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Cognitive disorder | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Depressed level of consciousness | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Dizziness | 1 | (0.1) | 1 | (0.1) | 6 | (0.4) | 7 | (0.3) |
| Encephalopathy | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Epilepsy | 0 | (0.0) | 0 | (0.0) | 5 | (0.3) | 5 | (0.2) |
| Guillain-Barre syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhage intracranial | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhagic stroke | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Nervous system disorders** | **23** | **(3.4)** | **34** | **(2.8)** | **74** | **(4.7)** | **108** | **(3.9)** |
| Headache | 3 | (0.4) | 3 | (0.2) | 10 | (0.6) | 13 | (0.5) |
| Hemiparesis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hemiplegia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hydrocephalus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Incoherent | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Intracranial aneurysm | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Ischaemic stroke | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Lethargy | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lumbar radiculopathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Meningitis noninfective | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Migraine with aura | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Monoparesis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myasthenic syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Myelitis transverse | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neuralgia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Neurological decompensation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Neuropathy peripheral | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Normal pressure hydrocephalus | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Paraesthesia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Partial seizures | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Peripheral motor neuropathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Presyncope | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Sciatica | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Seizure | 1 | (0.1) | 1 | (0.1) | 8 | (0.5) | 9 | (0.3) |
| Spinal cord compression | 2 | (0.3) | 3 | (0.2) | 9 | (0.6) | 12 | (0.4) |
| Syncope | 4 | (0.6) | 7 | (0.6) | 8 | (0.5) | 15 | (0.5) |
| Toxic leukoencephalopathy | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vasogenic cerebral oedema | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Psychiatric disorders** | **11** | **(1.6)** | **14** | **(1.1)** | **13** | **(0.8)** | **27** | **(1.0)** |
| Anxiety | 3 | (0.4) | 4 | (0.3) | 1 | (0.1) | 5 | (0.2) |
| Completed suicide | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Confusional state | 3 | (0.4) | 4 | (0.3) | 6 | (0.4) | 10 | (0.4) |
| Delirium | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Psychiatric disorders** | **11** | **(1.6)** | **14** | **(1.1)** | **13** | **(0.8)** | **27** | **(1.0)** |
| Depression | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Disorientation | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hallucination | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Insomnia | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Mental status changes | 2 | (0.3) | 2 | (0.2) | 2 | (0.1) | 4 | (0.1) |
| Nervousness | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Substance-induced psychotic disorder | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Renal and urinary disorders** | **10** | **(1.5)** | **18** | **(1.5)** | **20** | **(1.3)** | **38** | **(1.4)** |
| Acute kidney injury | 5 | (0.7) | 7 | (0.6) | 10 | (0.6) | 17 | (0.6) |
| Calculus ureteric | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dysuria | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haematuria | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Obstructive uropathy | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Postrenal failure | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Renal failure | 1 | (0.1) | 3 | (0.2) | 8 | (0.5) | 11 | (0.4) |
| Tubulointerstitial nephritis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urge incontinence | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary bladder polyp | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary retention | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Urinary tract obstruction | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Reproductive system and breast disorders** | **1** | **(0.1)** | **1** | **(0.1)** | **3** | **(0.2)** | **4** | **(0.1)** |
| Metrorrhagia | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pelvic pain | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pruritus genital | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Respiratory, thoracic and mediastinal disorders** | **83** | **(12.2)** | **158** | **(12.8)** | **86** | **(5.5)** | **244** | **(8.7)** |
| Acute respiratory failure | 2 | (0.3) | 6 | (0.5) | 1 | (0.1) | 7 | (0.3) |
| Atelectasis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Bronchial obstruction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Bronchostenosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Respiratory, thoracic and mediastinal disorders** | **83** | **(12.2)** | **158** | **(12.8)** | **86** | **(5.5)** | **244** | **(8.7)** |
| Chronic obstructive pulmonary disease | 8 | (1.2) | 12 | (1.0) | 2 | (0.1) | 14 | (0.5) |
| Cough | 4 | (0.6) | 4 | (0.3) | 2 | (0.1) | 6 | (0.2) |
| Diffuse alveolar damage | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Dysphonia | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Dyspnoea | 25 | (3.7) | 48 | (3.9) | 30 | (1.9) | 78 | (2.8) |
| Dyspnoea exertional | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) | 3 | (0.1) |
| Epistaxis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Haemoptysis | 4 | (0.6) | 5 | (0.4) | 4 | (0.3) | 9 | (0.3) |
| Haemothorax | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hiccups | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypercapnia | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Hypoxia | 5 | (0.7) | 8 | (0.6) | 4 | (0.3) | 12 | (0.4) |
| Interstitial lung disease | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Laryngeal inflammation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Lung consolidation | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Obstructive airways disorder | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Oesophagobronchial fistula | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Orthopnoea | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Painful respiration | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Pleural effusion | 10 | (1.5) | 23 | (1.9) | 14 | (0.9) | 37 | (1.3) |
| Pleuritic pain | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pneumonia aspiration | 3 | (0.4) | 3 | (0.2) | 1 | (0.1) | 4 | (0.1) |
| Pneumonitis | 14 | (2.1) | 24 | (1.9) | 10 | (0.6) | 34 | (1.2) |
| Pneumothorax | 0 | (0.0) | 3 | (0.2) | 2 | (0.1) | 5 | (0.2) |
| Pneumothorax spontaneous | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Productive cough | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pulmonary embolism | 18 | (2.6) | 31 | (2.5) | 15 | (1.0) | 46 | (1.6) |
| Pulmonary haemorrhage | 2 | (0.3) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| Pulmonary hypertension | 1 | (0.1) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Pulmonary infarction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Pulmonary oedema | 2 | (0.3) | 4 | (0.3) | 0 | (0.0) | 4 | (0.1) |
| Pulmonary thrombosis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |



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## Subjects With Grade 3-5 Adverse Events
## (Incidence > 0% in One or More Treatment Groups)
## PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
## (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Respiratory, thoracic and mediastinal disorders** | **83** | **(12.2)** | **158** | **(12.8)** | **86** | **(5.5)** | **244** | **(8.7)** |
| Pulmonary vascular disorder | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pulmonary venous thrombosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Respiratory acidosis | 2 | (0.3) | 2 | (0.2) | 0 | (0.0) | 2 | (0.1) |
| Respiratory distress | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Respiratory failure | 4 | (0.6) | 13 | (1.1) | 2 | (0.1) | 15 | (0.5) |
| Stridor | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Tachypnoea | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Wheezing | 1 | (0.1) | 2 | (0.2) | 1 | (0.1) | 3 | (0.1) |
| **Skin and subcutaneous tissue disorders** | **7** | **(1.0)** | **14** | **(1.1)** | **26** | **(1.7)** | **40** | **(1.4)** |
| Dermatitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Drug eruption | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Erythema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Erythema multiforme | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hyperkeratosis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Lichen planus | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Lichenoid keratosis | 0 | (0.0) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Pemphigoid | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Pruritus | 0 | (0.0) | 0 | (0.0) | 4 | (0.3) | 4 | (0.1) |
| Psoriasis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Rash | 2 | (0.3) | 4 | (0.3) | 5 | (0.3) | 9 | (0.3) |
| Rash erythematous | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Rash generalised | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Rash maculo-papular | 1 | (0.1) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Rash pruritic | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin lesion | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Skin mass | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Stevens-Johnson syndrome | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Urticaria | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| **Surgical and medical procedures** | **0** | **(0.0)** | **1** | **(0.1)** | **1** | **(0.1)** | **2** | **(0.1)** |
| Mitral valve replacement | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Skin neoplasm excision | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |



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# Subjects With Grade 3-5 Adverse Events
# (Incidence > 0% in One or More Treatment Groups)
# PN001, PN002, PN006 and PN010 Subjects Treated with MK-3475
# (APaT Population)

| | P010 | | PN001 Lung, PN010 | | PN001 Mel, PN002, PN006 | | PN001 PN002 PN006 PN010 | |
|---|---|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) | n | (%) |
| **Vascular disorders** | **26** | **(3.8)** | **40** | **(3.2)** | **44** | **(2.8)** | **84** | **(3.0)** |
| Aortic stenosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Aortic thrombosis | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Arterial thrombosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Deep vein thrombosis | 0 | (0.0) | 2 | (0.2) | 5 | (0.3) | 7 | (0.3) |
| Embolism | 3 | (0.4) | 9 | (0.7) | 1 | (0.1) | 10 | (0.4) |
| Femoral artery occlusion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Haematoma | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Haemorrhagic infarction | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hot flush | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Hypertension | 10 | (1.5) | 13 | (1.1) | 19 | (1.2) | 32 | (1.1) |
| Hypertensive crisis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Hypotension | 2 | (0.3) | 3 | (0.2) | 4 | (0.3) | 7 | (0.3) |
| Lymphoedema | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Orthostatic hypotension | 0 | (0.0) | 0 | (0.0) | 3 | (0.2) | 3 | (0.1) |
| Peripheral ischaemia | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Phlebitis | 0 | (0.0) | 0 | (0.0) | 2 | (0.1) | 2 | (0.1) |
| Poor venous access | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |
| Shock haemorrhagic | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Superior vena cava occlusion | 1 | (0.1) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Superior vena cava syndrome | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Thrombosis | 3 | (0.4) | 3 | (0.2) | 0 | (0.0) | 3 | (0.1) |
| Vasculitis | 0 | (0.0) | 1 | (0.1) | 0 | (0.0) | 1 | (0.0) |
| Vena cava thrombosis | 1 | (0.1) | 1 | (0.1) | 1 | (0.1) | 2 | (0.1) |
| Venous thrombosis | 0 | (0.0) | 0 | (0.0) | 1 | (0.1) | 1 | (0.0) |

Every subject is counted a single time for each applicable row and column.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.

MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.

Include all treated subjects in PN001 Part B1, B2, B3, D, C, F1, F2, F3 and all subjects in PN002 treated with Pembrolizumab in the original phase , and all subjects in PN006 and PN010 treated with Pembrolizumab.

(MK-3475 PN001 Database Cutoff Date for MEL: [redacted]).

(MK-3475 PN001 Database Cutoff Date for Lung: [redacted]).

(MK-3475 PN002 Database Cutoff Date: [redacted]).

(MK-3475 PN006 Database Cutoff Date: 03MAR2015).

(MK-3475 PN010 Database Cutoff Date: 30SEP2015).



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