|  |  |  |  |
| --- | --- | --- | --- |
| **Toxicity** | **n** | **Total** | **Incidence per 1 000** **person-years (95% CI)** |
| **Lactic acidosis** | 79 | 1 762 | 17 (14 to 21) |
| ***Females\**** | 72 | 1 225 | 23 (18 to 28) |
| < 40 kg | 1 | 24 | 16 (-15 to 47) |
| 40-49 kg | 4 | 175 | 9 (0 to 17) |
| 50-59 kg | 9 | 383 | 9 (3 to 15) |
| 60-69 kg | 26 | 359 | 28 (18 to 38) |
| 70-79 kg | 9 | 117 | 30 (11 to 48) |
| 80-89 kg | 12 | 76 | 69 (34 to105) |
| > 90 kg | 9 | 32 | 109 (48 to 167) |
| ***Males*** | 7 | 536 | 5 (1 to 9) |
| < 60 kg | 2 | 244 | 3 (-1 to 8) |
| 60-69 kg | 1 | 164 | 2 (-2 to 7) |
| 70-79 kg | 2 | 56 | 14 (-5 to 32) |
| > 80 kg | 2 | 40 | 19 (-7 to 46) |
| **Symptomatic hyperlactataemia** | 84 | 1 762 | 19 (15 to 22) |
| **Peripheral neuropathy** | 67 | 1 762 | 15 (11 to 18) |
| **Lipodystrophy** | 43 | 1 762 | 9 (7 to 12) |
| **Pancreatitis** | 2 | 1 762 | 0 (0 to1) |
| **Total** | 275 | 1 762 | 60 (54 to 67) |