



Clinical trial results:

A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When Evolocumab (AMG 145) is Used in Combination With Statin Therapy In Patients with Clinically Evident Cardiovascular Disease

Summary

| | |
|--------------------------|--|
| EudraCT number | 2012-001398-97 |
| Trial protocol | FI SK PL GR LT BE IT NL DK AT HU PT ES CZ EE IS GB DE BG |
| Global end of trial date | SE LV IE NO 11 November 2016 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 |
| This version publication date | 26 November 2017 |
| First version publication date | 26 November 2017 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | 20110118 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01764633 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Amgen Inc. |
| Sponsor organisation address | One Amgen Center Drive, Thousand Oaks, CA, United States, 91320 |
| Public contact | IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com |
| Scientific contact | IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 18 January 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 11 November 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the effect of treatment with evolocumab, compared with placebo, on the risk for cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization, whichever occurs first, in patients with clinically evident cardiovascular disease.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines. All subjects provided written informed consent before undergoing any study-related procedures, including screening procedures. The study and all amendments were reviewed by an independent ethics committees (IEC) or institutional review board (IRB) at each center.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 08 February 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Australia: 325 |
| Country: Number of subjects enrolled | China: 1021 |
| Country: Number of subjects enrolled | Hong Kong: 46 |
| Country: Number of subjects enrolled | India: 266 |
| Country: Number of subjects enrolled | Japan: 429 |
| Country: Number of subjects enrolled | Korea, Republic of: 181 |
| Country: Number of subjects enrolled | Malaysia: 65 |
| Country: Number of subjects enrolled | New Zealand: 92 |
| Country: Number of subjects enrolled | Philippines: 294 |
| Country: Number of subjects enrolled | Singapore: 35 |
| Country: Number of subjects enrolled | South Africa: 937 |
| Country: Number of subjects enrolled | Taiwan: 144 |
| Country: Number of subjects enrolled | Austria: 173 |
| Country: Number of subjects enrolled | Belgium: 245 |
| Country: Number of subjects enrolled | Bulgaria: 292 |
| Country: Number of subjects enrolled | Czech Republic: 2221 |
| Country: Number of subjects enrolled | Denmark: 481 |

| | |
|--------------------------------------|--------------------------|
| Country: Number of subjects enrolled | Estonia: 164 |
| Country: Number of subjects enrolled | Finland: 242 |
| Country: Number of subjects enrolled | France: 354 |
| Country: Number of subjects enrolled | Germany: 738 |
| Country: Number of subjects enrolled | Greece: 271 |
| Country: Number of subjects enrolled | Hungary: 980 |
| Country: Number of subjects enrolled | Iceland: 90 |
| Country: Number of subjects enrolled | Ireland: 55 |
| Country: Number of subjects enrolled | Israel: 239 |
| Country: Number of subjects enrolled | Italy: 393 |
| Country: Number of subjects enrolled | Latvia: 144 |
| Country: Number of subjects enrolled | Lithuania: 131 |
| Country: Number of subjects enrolled | Netherlands: 998 |
| Country: Number of subjects enrolled | Norway: 111 |
| Country: Number of subjects enrolled | Poland: 2467 |
| Country: Number of subjects enrolled | Portugal: 273 |
| Country: Number of subjects enrolled | Romania: 193 |
| Country: Number of subjects enrolled | Russian Federation: 1565 |
| Country: Number of subjects enrolled | Slovakia: 638 |
| Country: Number of subjects enrolled | Spain: 362 |
| Country: Number of subjects enrolled | Sweden: 474 |
| Country: Number of subjects enrolled | Switzerland: 175 |
| Country: Number of subjects enrolled | Turkey: 189 |
| Country: Number of subjects enrolled | Ukraine: 1186 |
| Country: Number of subjects enrolled | United Kingdom: 1491 |
| Country: Number of subjects enrolled | Argentina: 269 |
| Country: Number of subjects enrolled | Brazil: 693 |
| Country: Number of subjects enrolled | Chile: 196 |
| Country: Number of subjects enrolled | Colombia: 377 |
| Country: Number of subjects enrolled | Mexico: 288 |
| Country: Number of subjects enrolled | Canada: 558 |
| Country: Number of subjects enrolled | United States: 4013 |
| Worldwide total number of subjects | 27564 |
| EEA total number of subjects | 13981 |

Notes:

Subjects enrolled per age group

| | |
|---|-------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 15310 |
| From 65 to 84 years | 12225 |
| 85 years and over | 29 |

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at 1242 clinical centers in 49 countries in the regions of Europe (62.9%), North America (16.6%), Asia Pacific (13.9%), and Latin America (6.6%) from 08 February 2013 to 05 June 2015.

Pre-assignment

Screening details:

Eligible participants were randomized in a 1:1 ratio to receive either subcutaneous (SC) evolocumab or placebo. Randomization was stratified by the final screening low-density lipoprotein cholesterol (LDL-C) level (< 85 mg/dL vs ≥ 85 mg/dL) and by geographical region.

Period 1

| | |
|------------------------------|---|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Data analyst, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference.

| | |
|--|--|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Administered subcutaneously using a spring-based prefilled 1.0 mL autoinjector/pen.

| | |
|------------------|------------|
| Arm title | Evolocumab |
|------------------|------------|

Arm description:

Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Evolocumab |
| Investigational medicinal product code | AMG 145 |
| Other name | Repatha |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Administered subcutaneously at 140 mg Q2W or 420 mg QM using a spring-based prefilled 1.0 mL autoinjector/pen.

| Number of subjects in period 1 | Placebo | Evolocumab |
|---------------------------------------|---------|------------|
| Started | 13780 | 13784 |
| Received Treatment | 13756 | 13769 |
| Completed | 13662 | 13691 |
| Not completed | 118 | 93 |
| Consent withdrawn by subject | 105 | 88 |
| Lost to follow-up | 13 | 5 |

Baseline characteristics

Reporting groups

| | |
|---|------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference. | |
| Reporting group title | Evolocumab |
| Reporting group description: | |
| Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference. | |

| Reporting group values | Placebo | Evolocumab | Total |
|---|---------|------------|-------|
| Number of subjects | 13780 | 13784 | 27564 |
| Age, Customized | | | |
| Units: Subjects | | | |
| < 65 years | 7687 | 7623 | 15310 |
| ≥ 65 years | 6093 | 6161 | 12254 |
| Age Continuous | | | |
| Units: years | | | |
| arithmetic mean | 62.5 | 62.5 | |
| standard deviation | ± 8.9 | ± 9.1 | - |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 3382 | 3387 | 6769 |
| Male | 10398 | 10397 | 20795 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 80 | 60 | 140 |
| Asian | 1349 | 1374 | 2723 |
| Black or African American | 352 | 317 | 669 |
| Native Hawaiian or Other Pacific Islander | 11 | 15 | 26 |
| White | 11710 | 11748 | 23458 |
| Multiple | 12 | 19 | 31 |
| Other | 266 | 251 | 517 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 1084 | 1093 | 2177 |
| Not Hispanic or Latino | 12694 | 12688 | 25382 |
| Unknown or Not Reported | 2 | 3 | 5 |
| Final Screening Low-density Lipoprotein Cholesterol | | | |
| Units: Subjects | | | |
| < 85 mg/dL | 4803 | 4809 | 9612 |
| ≥ 85 mg/dL | 8977 | 8975 | 17952 |
| Geographical Region | | | |
| Units: Subjects | | | |
| Europe | 8669 | 8667 | 17336 |
| North America | 2284 | 2286 | 4570 |

| | | | |
|---------------|------|------|------|
| Latin America | 910 | 913 | 1823 |
| Asia Pacific | 1917 | 1918 | 3835 |

End points

End points reporting groups

| | |
|---|------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference. | |
| Reporting group title | Evolocumab |
| Reporting group description: | |
| Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference. | |

Primary: Time to Cardiovascular Death, Myocardial Infarction, Hospitalization for Unstable Angina, Stroke, or Coronary Revascularization

| | |
|---|---|
| End point title | Time to Cardiovascular Death, Myocardial Infarction, Hospitalization for Unstable Angina, Stroke, or Coronary Revascularization |
| End point description: | |
| All deaths and potential endpoint events were adjudicated by an independent external Clinical Events Committee (CEC) led by the Thrombolysis in Myocardial Infarction (TIMI) Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Time to cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization was defined as the time from randomization to the first occurrence of any component of the composite endpoint and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date. | |
| End point type | Primary |
| End point timeframe: | |
| Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported. | |

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 3.11 (2.82 to 3.40) | 2.74 (2.47 to 3.01) | | |
| KM estimate at 12 months | 6.01 (5.61 to 6.41) | 5.31 (4.93 to 5.68) | | |
| KM estimate at 18 months | 8.32 (7.86 to 8.78) | 7.25 (6.81 to 7.68) | | |
| KM estimate at 24 months | 10.66 (10.12 to 11.19) | 9.13 (8.63 to 9.63) | | |
| KM estimate at 30 months | 12.72 (12.08 to 13.35) | 10.91 (10.31 to 11.50) | | |
| KM estimate at 36 months | 14.64 (13.76 to 15.50) | 12.57 (11.70 to 13.42) | | |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Primary Analysis |
| Statistical analysis description: | |
| The primary endpoint was compared between treatment groups at a significance level of 0.05. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region). | |
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[1] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.85 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 0.92 |

Notes:

[1] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to Cardiovascular Death, Myocardial Infarction, or Stroke

| | |
|--|--|
| End point title | Time to Cardiovascular Death, Myocardial Infarction, or Stroke |
| End point description: | |
| All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Time to cardiovascular death, myocardial infarction, or stroke was defined as the time from randomization to the first occurrence of any component of the composite endpoint and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date. | |
| End point type | Secondary |
| End point timeframe: | |
| Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported. | |

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|----------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 1.86 (1.63 to 2.08) | 1.65 (1.44 to 1.86) | | |
| KM estimate at 12 months | 3.68 (3.36 to 3.99) | 3.10 (2.81 to 3.38) | | |
| KM estimate at 18 months | 5.18 (4.81 to 5.55) | 4.29 (3.95 to 4.62) | | |
| KM estimate at 24 months | 6.83 (6.39 to 7.26) | 5.47 (5.08 to 5.86) | | |
| KM estimate at 30 months | 8.31 (7.78 to 8.84) | 6.66 (6.19 to 7.14) | | |
| KM estimate at 36 months | 9.93 (9.16 to 10.69) | 7.90 (7.17 to 8.63) | | |

Statistical analyses

| Statistical analysis title | Primary Analysis |
|---|-------------------------|
| Statistical analysis description: | |
| If the primary endpoint reached statistical significance at the 0.05 level, the key secondary endpoint (composite of cardiovascular death, myocardial infarction, and stroke) was tested at a significance level of 0.05. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region). | |
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[2] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.73 |
| upper limit | 0.88 |

Notes:

[2] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to Cardiovascular Death

| | |
|-----------------|------------------------------|
| End point title | Time to Cardiovascular Death |
|-----------------|------------------------------|

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Cardiovascular death includes death resulting from an acute myocardial infarction (MI), sudden cardiac death, death due to heart failure (HF), death due to stroke, death due to cardiovascular (CV) procedures, death due to CV hemorrhage, and death due to other CV causes. Time to cardiovascular death was defined as the time from randomization to the date of cardiovascular death and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of

participants with an event are reported. Participants with no event were censored based on the last confirmed survival status date.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 0.40 (0.29 to 0.50) | 0.39 (0.29 to 0.50) | | |
| KM estimate at 12 months | 0.82 (0.67 to 0.97) | 0.79 (0.64 to 0.94) | | |
| KM estimate at 18 months | 1.19 (1.01 to 1.37) | 1.20 (1.01 to 1.38) | | |
| KM estimate at 24 months | 1.57 (1.36 to 1.79) | 1.64 (1.42 to 1.85) | | |
| KM estimate at 30 months | 1.99 (1.72 to 2.26) | 2.11 (1.83 to 2.39) | | |
| KM estimate at 36 months | 2.39 (1.98 to 2.80) | 2.49 (2.09 to 2.88) | | |

Statistical analyses

| | |
|----------------------------|------------------|
| Statistical analysis title | Primary Analysis |
|----------------------------|------------------|

Statistical analysis description:

If the primary and key secondary endpoint reached a statistical significance level of 0.05, then the endpoint of cardiovascular death was tested at a significance level of 0.05. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

| | |
|---|-------------------------|
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.6188 ^[3] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.88 |
| upper limit | 1.25 |

Notes:

[3] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to All Cause Death

| | |
|-----------------|-------------------------|
| End point title | Time to All Cause Death |
|-----------------|-------------------------|

End point description:

Time to all-cause death was defined as the time from randomization to the date of death and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on the last confirmed survival status date.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 0.62 (0.49 to 0.75) | 0.55 (0.43 to 0.68) | | |
| KM estimate at 12 months | 1.29 (1.10 to 1.47) | 1.26 (1.07 to 1.44) | | |
| KM estimate at 18 months | 1.96 (1.73 to 2.19) | 1.94 (1.71 to 2.17) | | |
| KM estimate at 24 months | 2.78 (2.49 to 3.06) | 2.81 (2.52 to 3.10) | | |
| KM estimate at 30 months | 3.48 (3.12 to 3.83) | 3.63 (3.27 to 3.98) | | |
| KM estimate at 36 months | 4.28 (3.74 to 4.82) | 4.75 (4.16 to 5.34) | | |

Statistical analyses

| | |
|----------------------------|------------------|
| Statistical analysis title | Primary Analysis |
|----------------------------|------------------|

Statistical analysis description:

If the primary, key secondary and endpoint cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints at an overall significant level of 0.01 by applying the Hochberg method. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

| | |
|---|-------------------------|
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5368 ^[4] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.04 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.91 |
| upper limit | 1.19 |

Notes:

[4] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Myocardial Infarction

| | |
|-----------------|-------------------------------------|
| End point title | Time to First Myocardial Infarction |
|-----------------|-------------------------------------|

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". The diagnosis of myocardial infarction required the combination of: • Evidence of myocardial necrosis (either changes in cardiac biomarkers or post-mortem pathological findings); and • Supporting information derived from the clinical presentation, electrocardiographic changes, or the results of myocardial or coronary artery Imaging. Time to first myocardial infarction was defined as the time from randomization to the date of the first MI and was analyzed using Kaplan-Meier survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 1.14 (0.97 to 1.32) | 1.06 (0.88 to 1.23) | | |
| KM estimate at 12 months | 2.39 (2.13 to 2.64) | 1.90 (1.67 to 2.13) | | |
| KM estimate at 18 months | 3.33 (3.03 to 3.63) | 2.55 (2.28 to 2.81) | | |
| KM estimate at 24 months | 4.30 (3.95 to 4.65) | 3.21 (2.90 to 3.51) | | |
| KM estimate at 30 months | 5.25 (4.82 to 5.67) | 3.83 (3.47 to 4.19) | | |
| KM estimate at 36 months | 6.28 (5.67 to 6.89) | 4.41 (3.85 to 4.96) | | |

Statistical analyses

| | |
|----------------------------|------------------|
| Statistical analysis title | Primary Analysis |
|----------------------------|------------------|

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the

Hochberg method. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

| | |
|---|-------------------------|
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[5] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.73 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.65 |
| upper limit | 0.82 |

Notes:

[5] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Stroke

| | |
|--|----------------------|
| End point title | Time to First Stroke |
| End point description: | |
| All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Stroke was defined as an acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction. Time to first stroke was defined as the time from randomization to the date of the stroke and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date. | |
| End point type | Secondary |
| End point timeframe: | |
| Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported. | |

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 0.50 (0.38 to 0.61) | 0.31 (0.22 to 0.41) | | |
| KM estimate at 12 months | 0.85 (0.69 to 1.00) | 0.70 (0.56 to 0.84) | | |
| KM estimate at 18 months | 1.30 (1.11 to 1.50) | 1.05 (0.88 to 1.22) | | |
| KM estimate at 24 months | 1.80 (1.57 to 2.04) | 1.36 (1.16 to 1.56) | | |
| KM estimate at 30 months | 2.15 (1.88 to 2.43) | 1.71 (1.46 to 1.96) | | |
| KM estimate at 36 months | 2.60 (2.20 to 3.00) | 2.18 (1.76 to 2.59) | | |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Primary Analysis |
| Statistical analysis description: | |
| If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region). | |
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0101 ^[6] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.79 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.66 |
| upper limit | 0.95 |

Notes:

[6] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Coronary Revascularization

| | |
|---|--|
| End point title | Time to First Coronary Revascularization |
| End point description: | |
| All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions based on the "Standardized Definitions for Cardiovascular and Stroke End Point Events in Clinical Trials and the Third Universal Definition of Myocardial Infarction". Time to first coronary revascularization was defined as the time from randomization to the date of the coronary revascularization and was analyzed using Kaplan-Meier (KM) survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date. | |
| End point type | Secondary |
| End point timeframe: | |
| Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported. | |

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 1.87 (1.65 to 2.10) | 1.60 (1.39 to 1.81) | | |
| KM estimate at 12 months | 3.71 (3.39 to 4.02) | 3.13 (2.84 to 3.42) | | |
| KM estimate at 18 months | 5.20 (4.82 to 5.57) | 4.16 (3.83 to 4.50) | | |
| KM estimate at 24 months | 6.57 (6.14 to 7.00) | 5.22 (4.84 to 5.61) | | |
| KM estimate at 30 months | 7.91 (7.39 to 8.42) | 6.13 (5.68 to 6.58) | | |
| KM estimate at 36 months | 9.17 (8.46 to 9.87) | 7.01 (6.36 to 7.65) | | |

Statistical analyses

| Statistical analysis title | Primary Analysis |
|---|-------------------------|
| Statistical analysis description: | |
| If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region). | |
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[7] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.78 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.71 |
| upper limit | 0.86 |

Notes:

[7] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to Cardiovascular Death or First Hospitalization for Worsening Heart Failure

| | |
|-----------------|---|
| End point title | Time to Cardiovascular Death or First Hospitalization for Worsening Heart Failure |
|-----------------|---|

End point description:

All events were adjudicated by an independent external CEC led by the TIMI Study Group using standardized definitions. HF hospitalization was defined as an event that met all of the following criteria: 1. Admitted to hospital with a primary diagnosis of HF 2. In hospital for at least 24 hours 3. Documented new or worsening symptoms due to HF, including at least 1 of the following: - Dyspnea - Decreased exercise tolerance - Fatigue - Other symptoms of worsened end-organ perfusion or volume overload 4.

Evidence of new or worsening HF consisting of at least 2 physical exam findings or 1 physical exam finding and at least 1 laboratory criterion 5. Received new or increased treatment for HF. Time to CV death or first hospitalization for worsening HF was defined as the time from randomization to the first occurrence of any component of the endpoint analyzed using KM analysis. Participants with no event were censored based on last non-fatal potential endpoint collection date.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 0.79 (0.64 to 0.93) | 0.64 (0.51 to 0.77) | | |
| KM estimate at 12 months | 1.35 (1.16 to 1.54) | 1.29 (1.10 to 1.48) | | |
| KM estimate at 18 months | 1.99 (1.75 to 2.22) | 1.99 (1.76 to 2.22) | | |
| KM estimate at 24 months | 2.70 (2.41 to 2.98) | 2.64 (2.36 to 2.92) | | |
| KM estimate at 30 months | 3.45 (3.09 to 3.81) | 3.31 (2.97 to 3.65) | | |
| KM estimate at 36 months | 4.03 (3.50 to 4.55) | 4.13 (3.57 to 4.68) | | |

Statistical analyses

| | |
|----------------------------|------------------|
| Statistical analysis title | Primary Analysis |
|----------------------------|------------------|

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

| | |
|---|-------------------------|
| Comparison groups | Placebo v Evolocumab |
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.8179 ^[8] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.13 |

Notes:

[8] - Two-sided log-rank test stratified by randomization stratification factors.

Secondary: Time to First Ischemic Fatal or non-Fatal Stroke or Transient Ischemic Attack

| | |
|-----------------|---|
| End point title | Time to First Ischemic Fatal or non-Fatal Stroke or Transient Ischemic Attack |
|-----------------|---|

End point description:

All deaths and potential endpoint events were adjudicated by an independent external CEC led by the TIMI Study Group, using standardized definitions. Ischemic stroke was defined as an acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of central nervous system tissue. Transient ischemic attack (TIA) was defined as a transient episode of focal neurological dysfunction caused by brain, spinal cord, or retinal ischemia, without acute infarction. Time to first ischemic fatal or non-fatal stroke or TIA was defined as the time from randomization to the first occurrence of any component of the endpoint and was analyzed using KM survival analysis. KM estimates of the percentage of participants with an event are reported. Participants with no event were censored based on last non-fatal potential endpoint collection date.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Events that occurred from randomization to the last confirmed survival status date; the median duration of follow-up was 26 months. KM estimates at 6, 12, 18, 24, 30 and 36 months are reported.

| End point values | Placebo | Evolocumab | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13780 | 13784 | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| KM estimate at 6 months | 0.61 (0.48 to 0.73) | 0.42 (0.31 to 0.53) | | |
| KM estimate at 12 months | 1.05 (0.88 to 1.22) | 0.83 (0.67 to 0.98) | | |
| KM estimate at 18 months | 1.52 (1.32 to 1.73) | 1.18 (1.00 to 1.37) | | |
| KM estimate at 24 months | 2.05 (1.81 to 2.30) | 1.46 (1.25 to 1.66) | | |
| KM estimate at 30 months | 2.40 (2.11 to 2.68) | 1.92 (1.65 to 2.19) | | |
| KM estimate at 36 months | 2.81 (2.41 to 3.21) | 2.48 (2.01 to 2.95) | | |

Statistical analyses

| | |
|----------------------------|------------------|
| Statistical analysis title | Primary Analysis |
|----------------------------|------------------|

Statistical analysis description:

If the primary, key secondary, and endpoint of cardiovascular death reached a statistical significance level of 0.05, then the endpoint of all-cause death was tested at a significance level of 0.04 and remaining secondary endpoints were tested at an overall significance level of 0.01 by applying the Hochberg method. The hazard ratio is based on a Cox model stratified by the randomization stratification factors (final screening LDL-C level and region).

| | |
|-------------------|----------------------|
| Comparison groups | Placebo v Evolocumab |
|-------------------|----------------------|

| | |
|---|-------------------------|
| Number of subjects included in analysis | 27564 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0035 ^[9] |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.65 |
| upper limit | 0.92 |

Notes:

[9] - Two-sided log-rank test stratified by randomization stratification factors.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose of study drug to the end of study. The median duration of follow-up was 26 months.

Adverse event reporting additional description:

Deaths by any cause were adjudicated efficacy endpoints in this study and were summarized as a secondary endpoint. Events that were negatively adjudicated (did not meet the definitions of an endpoint), were reclassified as an adverse event or serious adverse event.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 19.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | Evolocumab |
|-----------------------|------------|

Reporting group description:

Participants received evolocumab subcutaneous injections either 140 mg Q2W or 420 mg QM according to their own preference.

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Participants received placebo subcutaneous injections either once every 2 weeks (Q2W) or once a month (QM) according to their own preference.

| Serious adverse events | Evolocumab | Placebo | |
|---|--------------------------|--------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3410 / 13769 (24.77%) | 3404 / 13756 (24.75%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute leukaemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma gastric | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of appendix | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of colon | | | |
| subjects affected / exposed | 17 / 13769 (0.12%) | 12 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 17 | 1 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma pancreas | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal adenoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal gland cancer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal cancer stage III | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal neoplasm | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anogenital warts | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| B-cell lymphoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| B-cell lymphoma stage I | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| B-cell polymphocytic leukaemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basosquamous carcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign gastric neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign gastrointestinal neoplasm | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign lung neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of adrenal gland | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of bladder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of prostate | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of spinal cord | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign pancreatic neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign renal neoplasm | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct cancer | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary adenoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder adenocarcinoma stage III | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder adenocarcinoma stage unspecified | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 12 / 13769 (0.09%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer recurrent | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer stage 0, with cancer in situ | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer stage I, with cancer in situ | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer stage III | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder papilloma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma recurrent | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma stage I | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma stage II | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma stage III | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-------------------|-------------------|--|
| Bladder transitional cell carcinoma stage IV | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bowen's disease | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain cancer metastatic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm malignant | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer female | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer in situ | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer recurrent | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial carcinoma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burkitt's lymphoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carcinoid tumour pulmonary | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangiocarcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholesteatoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Choroid melanoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clear cell renal cell carcinoma | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon adenoma | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer stage I | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer stage III | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon neoplasm | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal adenocarcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer metastatic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatofibrosarcoma protuberans | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diffuse large B-cell lymphoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ductal adenocarcinoma of pancreas | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial adenocarcinoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial adenoma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fallopian tube cancer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibroma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Follicular thyroid cancer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric adenoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer stage 0 | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer stage IV | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal carcinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stromal tumour | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma multiforme | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemangiopericytoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic neoplasm | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hodgkin's disease | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal papillary mucinous neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal papillary-mucinous carcinoma of pancreas | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive breast carcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large cell lung cancer stage III | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal cancer | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal cancer metastatic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal cancer stage 0 | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal cancer stage IV | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip and/or oral cavity cancer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip and/or oral cavity cancer stage III | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip squamous cell carcinoma | | | |

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|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liposarcoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 13 / 13769 (0.09%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma metastatic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma stage I | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma stage III | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma stage IV | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung cancer metastatic | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung carcinoma cell type unspecified stage I | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung carcinoma cell type unspecified stage II | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung carcinoma cell type unspecified stage III | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung carcinoma cell type unspecified stage IV | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 19 / 13769 (0.14%) | 15 / 13756 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 21 | 1 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung squamous cell carcinoma metastatic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|-------------------|-------------------|--|
| Lung squamous cell carcinoma stage I | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung squamous cell carcinoma stage III | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoproliferative disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant anorectal neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant ascites | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma in situ | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma of sites other | | | |

| | | | |
|---|-------------------|-------------------|--|
| than skin | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant mesenteric neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant neoplasm of pleura | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant neoplasm of renal pelvis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant peritoneal neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant urinary tract neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma benign | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesothelioma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesothelioma malignant | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to adrenals | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to liver | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to lung | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to lymph nodes | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to pleura | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to spine | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastasis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic bronchial carcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic malignant melanoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelofibrosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm malignant | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm progression | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm prostate | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma metastatic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine tumour | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer metastatic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal adenocarcinoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal adenocarcinoma metastatic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal carcinoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral cavity cancer metastatic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral papilloma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal cancer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian adenoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cancer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cancer stage II | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian epithelial cancer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic carcinoma metastatic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary cystadenoma lymphomatosum | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary thyroid cancer | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parathyroid tumour benign | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Penile cancer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phaeochromocytoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal cancer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal cancer stage IV | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal neoplasm benign | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma cell myeloma | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasmacytoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural mesothelioma malignant | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polycythaemia vera | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 41 / 13769 (0.30%) | 40 / 13756 (0.29%) | |
| occurrences causally related to treatment / all | 3 / 42 | 0 / 42 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 6 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer stage I | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer stage II | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer stage IV | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic adenoma | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer stage III | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer stage IV | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal adenoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 9 / 13769 (0.07%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 11 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer metastatic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer stage I | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma stage I | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma stage II | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma stage III | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal oncocytoma | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal neoplasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland adenoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoma metastatic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schwannoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin cancer | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer limited stage | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer metastatic | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestine carcinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue sarcoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spindle cell sarcoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of head and neck | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of skin | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 5 / 13769 (0.04%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the oral cavity | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the tongue | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the vulva | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid cancer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid cancer metastatic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue neoplasm malignant stage unspecified | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsil cancer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|-------------------|-------------------|--|
| Transitional cell cancer of the renal pelvis and ureter | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tumour haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Undifferentiated sarcoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteral neoplasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord neoplasm | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval cancer recurrent | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aneurysm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiopathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiosclerosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 27 / 13769 (0.20%) | 27 / 13756 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 28 | 0 / 28 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm rupture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stenosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 7 / 13769 (0.05%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic thrombosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure fluctuation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Circulatory collapse | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cryoglobulinaemia | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 14 / 13756 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic vascular disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dry gangrene | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism arterial | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granulomatosis with polyangiitis | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 56 / 13769 (0.41%) | 41 / 13756 (0.30%) | |
| occurrences causally related to treatment / all | 2 / 59 | 1 / 41 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 15 / 13769 (0.11%) | 12 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 1 / 12 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemic shock | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iliac artery occlusion | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 5 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermittent claudication | | | |
| subjects affected / exposed | 31 / 13769 (0.23%) | 22 / 13756 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 41 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Internal haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leriche syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphocele | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoedema | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant hypertension | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurogenic shock | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic hypotension | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 9 / 13769 (0.07%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic venous thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 94 / 13769 (0.68%) | 82 / 13756 (0.60%) | |
| occurrences causally related to treatment / all | 1 / 113 | 0 / 96 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery dissection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 20 / 13769 (0.15%) | 16 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 27 / 13769 (0.20%) | 33 / 13756 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 30 | 0 / 37 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral circulatory failure | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral embolism | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral ischaemia | | | |
| subjects affected / exposed | 35 / 13769 (0.25%) | 39 / 13756 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 41 | 0 / 47 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral venous disease | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Poor peripheral circulation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renovascular hypertension | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian artery embolism | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian artery occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian artery stenosis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian steal syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Superior vena cava syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Takayasu's arteritis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Temporal arteritis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thromboangiitis obliterans | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis superficial | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicose ulceration | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicose vein | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular insufficiency | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stenosis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vasodilatation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vena cava thrombosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Abscess drainage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve replacement | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia prophylaxis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial catheterisation | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula operation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma prophylaxis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ablation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac pacemaker insertion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac rehabilitation therapy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac resynchronisation therapy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary arterial stent insertion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery bypass | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary revascularisation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Elective procedure | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterostomy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Finger amputation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture treatment | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric banding reversal | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemostasis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hospitalisation | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implantable defibrillator insertion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia repair | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia repair | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Knee arthroplasty | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal polypectomy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine anastomosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leg amputation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Open reduction of fracture | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Percutaneous coronary intervention | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery bypass | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plastic surgery to the face | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Preoperative care | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctectomy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rehabilitation therapy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal anaesthesia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stent placement | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Therapy cessation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toe amputation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transcatheter aortic valve implantation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transurethral prostatectomy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia repair | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral operation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breakthrough pain | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter site extravasation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 42 / 13769 (0.31%) | 49 / 13756 (0.36%) | |
| occurrences causally related to treatment / all | 0 / 43 | 1 / 53 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complication associated with device | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyst rupture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug intolerance | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug withdrawal syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exercise tolerance decreased | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fat necrosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fatigue | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired healing | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site inflammation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated hernia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mass | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device discomfort | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-cardiac chest pain | | | |

| | | | |
|---|------------------------|------------------------|--|
| subjects affected / exposed | 109 / 13769 (0.79%) | 133 / 13756 (0.97%) | |
| occurrences causally related to treatment / all | 1 / 125 | 0 / 152 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pacemaker generated arrhythmia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue inflammation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strangulated hernia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden cardiac death | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical failure | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic inflammatory response syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent restenosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent stenosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Allergy to arthropod sting | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic shock | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mite allergy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoidosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transplant rejection | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Abstains from alcohol | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disability | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social stay hospitalisation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Substance abuser | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Adnexa uteri mass | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 30 / 13769 (0.22%) | 26 / 13756 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 30 | 0 / 28 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast dysplasia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-------------------|-------------------|--|
| Breast enlargement | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast pain | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical dysplasia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical polyp | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystocele | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial thickening | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genital haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Male genital tract fistula | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Menorrhagia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metrorrhagia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postmenopausal haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Priapism | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive tract disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal cyst | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal oedema | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spermatic cord inflammation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine atony | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine enlargement | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine polyp | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine prolapse | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal prolapse | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulvar dysplasia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulvovaginal pruritus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acquired diaphragmatic eventration | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute pulmonary oedema | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Apnoea | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma-chronic obstructive pulmonary disease overlap syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atelectasis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial fistula | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiectasis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis chronic | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 64 / 13769 (0.46%) | 64 / 13756 (0.47%) | |
| occurrences causally related to treatment / all | 0 / 71 | 1 / 80 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Combined pulmonary fibrosis and emphysema | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diaphragmatic paralysis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphonia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 28 / 13769 (0.20%) | 18 / 13756 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 28 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea at rest | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysema | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiglottic cyst | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 7 / 13769 (0.05%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiccups | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperventilation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Idiopathic pulmonary fibrosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal oedema | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung disorder | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal cyst | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal obstruction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal polyps | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal septum deviation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal turbinate hypertrophy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nocturnal dyspnoea | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthopnoea | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal cyst | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pickwickian syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural adhesion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleurisy | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia aspiration | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 8 / 13769 (0.06%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 10 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Productive cough | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary alveolar haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary congestion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 20 / 13769 (0.15%) | 28 / 13756 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 20 | 1 / 29 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary fibrosis | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep apnoea syndrome | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 6 / 13769 (0.04%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stridor | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord leukoplakia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Acute psychosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Affective disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol abuse | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholism | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety disorder due to a general medical condition | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burnout syndrome | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional state | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conversion disorder | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium tremens | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |
| subjects affected / exposed | 15 / 13769 (0.11%) | 20 / 13756 (0.15%) | |
| occurrences causally related to treatment / all | 1 / 16 | 0 / 25 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression suicidal | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug abuse | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug dependence | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hallucination | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hallucination, visual | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Major depression | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mania | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mood disorder due to a general medical condition | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Panic attack | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Personality disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric decompensation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychogenic seizure | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Somatic symptom disorder | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device battery issue | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device breakage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device dislocation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device failure | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device ineffective | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device leakage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device loosening | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device malfunction | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lead dislodgement | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis in device | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Acute hepatic failure | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ampulla of Vater stenosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct obstruction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stone | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 1 / 5 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary cyst | | | |

| | | |
|---|--------------------|--------------------|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholangitis | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 2 / 13756 (0.01%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholangitis acute | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 6 / 13756 (0.04%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholecystitis | | |
| subjects affected / exposed | 14 / 13769 (0.10%) | 7 / 13756 (0.05%) |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholecystitis acute | | |
| subjects affected / exposed | 40 / 13769 (0.29%) | 31 / 13756 (0.23%) |
| occurrences causally related to treatment / all | 1 / 40 | 0 / 31 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholecystitis chronic | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholecystochoolangitis | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholelithiasis | | |
| subjects affected / exposed | 27 / 13769 (0.20%) | 23 / 13756 (0.17%) |
| occurrences causally related to treatment / all | 0 / 28 | 0 / 24 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cholelithiasis migration | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis obstructive | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cirrhosis alcoholic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug-induced liver injury | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder perforation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder polyp | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cirrhosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cyst | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic failure | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic fibrosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis acute | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis alcoholic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis toxic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatorenal syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatotoxicity | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Porcelain gallbladder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal vein thrombosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subacute hepatic failure | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 15 / 13756 (0.11%) | |
| occurrences causally related to treatment / all | 6 / 11 | 11 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriogram coronary | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriogram coronary abnormal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriogram coronary normal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 6 | 7 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatine phosphokinase increased | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 7 / 13769 (0.05%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 5 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose decreased | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose fluctuation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose increased | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure increased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac stress test abnormal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ejection fraction decreased | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram ST segment depression | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram abnormal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exercise electrocardiogram abnormal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| False positive investigation result | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart rate increased | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart rate irregular | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 24 / 13769 (0.17%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 14 / 25 | 4 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis A antibody positive | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis A virus test positive | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis B antibody positive | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis C virus test positive | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza A virus test positive | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio abnormal | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 3 / 7 | 2 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test increased | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical observation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial necrosis marker increased | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oxygen saturation decreased | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Precancerous cells present | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress echocardiogram | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid function test abnormal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transaminases increased | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 2 / 7 | 2 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin I increased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin T increased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin increased | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decreased | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight increased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Abdominal injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental overdose | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acetabulum fracture | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol poisoning | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia postoperative | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic fistula | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic leak | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic stenosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Animal bite | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Animal scratch | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 12 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial bypass occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial bypass thrombosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial injury | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial restenosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula site complication | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Avulsion fracture | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back injury | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbon monoxide poisoning | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery restenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cartilage injury | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical vertebral fracture | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chemical burn of gastrointestinal tract | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chemical poisoning | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest injury | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Comminuted fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery restenosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cranial nerve injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diffuse axonal injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dislocation of sternum | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dislocation of vertebra | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endotracheal intubation complication | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural haematoma | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye operation complication | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Face injury | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial bones fracture | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 17 / 13769 (0.12%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 20 / 13769 (0.15%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 20 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Forearm fracture | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body aspiration | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture displacement | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fractured ischium | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fractured sacrum | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft complication | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heat exhaustion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heat stroke | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 13769 (0.04%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ilium fracture | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incomplete spinal fusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammation of wound | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional overdose | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaw fracture | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation postoperative | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint injury | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney contusion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laceration | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament rupture | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb crushing injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb fracture | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb traumatic amputation | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medication error | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 8 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metal poisoning | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple fractures | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple injuries | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle contusion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle rupture | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Open globe injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Overdose | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patella fracture | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial reocclusion | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery restenosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 3 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirenal haematoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peroneal nerve palsy postoperative | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumoconiosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis chemical | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax traumatic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Poisoning | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post concussion syndrome | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post laminectomy syndrome | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural constipation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematuria | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural myocardial infarction | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural swelling | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic neck syndrome | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative respiratory failure | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative thoracic procedure complication | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound complication | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural complication | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural hypotension | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pneumothorax | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pubis fracture | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radial head dislocation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiation mucositis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiation oesophagitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 7 / 13769 (0.05%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sacroiliac fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scapula fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seroma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skeletal injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin abrasion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fracture | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fractured base | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Snake bite | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column injury | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord injury | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord injury lumbar | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic injury | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stab wound | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sternal fracture | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous haematoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haematoma | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon injury | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon rupture | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal burn | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transplant failure | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic arthritis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic fracture | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haematoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haemothorax | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic intracranial haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic shock | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic ulcer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulna fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulnar nerve injury | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper limb fracture | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stricture postoperative | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular bypass dysfunction | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft complication | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft occlusion | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft thrombosis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular procedure complication | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound dehiscence | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound evisceration | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound necrosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound secretion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Adenomatous polyposis coli | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous malformation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial septal defect | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbohydrate metabolism disorder | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Corneal dystrophy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exomphalos | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal arteriovenous malformation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hereditary motor and sensory neuropathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocele | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic cardiomyopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial lipoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subependymal nodular heterotopia | | | |

| | | | |
|---|---------------------|---------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute left ventricular failure | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 23 / 13756 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 11 | 1 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina pectoris | | | |
| subjects affected / exposed | 208 / 13769 (1.51%) | 221 / 13756 (1.61%) | |
| occurrences causally related to treatment / all | 4 / 240 | 6 / 250 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |
| subjects affected / exposed | 233 / 13769 (1.69%) | 278 / 13756 (2.02%) | |
| occurrences causally related to treatment / all | 4 / 273 | 3 / 314 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve disease | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve incompetence | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |

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|---|---------------------|---------------------|--|
| subjects affected / exposed | 10 / 13769 (0.07%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia supraventricular | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteritis coronary | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 119 / 13769 (0.86%) | 132 / 13756 (0.96%) | |
| occurrences causally related to treatment / all | 0 / 157 | 2 / 155 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial flutter | | | |
| subjects affected / exposed | 25 / 13769 (0.18%) | 17 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 27 | 1 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial tachycardia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial thrombosis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 16 | 1 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bifascicular block | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradyarrhythmia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 1 / 10 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block bilateral | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block left | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block right | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac aneurysm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac asthma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure | | | |
| subjects affected / exposed | 66 / 13769 (0.48%) | 66 / 13756 (0.48%) | |
| occurrences causally related to treatment / all | 0 / 71 | 1 / 73 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure acute | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 13 / 13769 (0.09%) | 10 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 13 | 1 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure chronic | | | |
| subjects affected / exposed | 50 / 13769 (0.36%) | 47 / 13756 (0.34%) | |
| occurrences causally related to treatment / all | 0 / 53 | 0 / 56 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 46 / 13769 (0.33%) | 37 / 13756 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 48 | 0 / 40 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac flutter | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac tamponade | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ventricular thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiomyopathy | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiorenal syndrome | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiotoxicity | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiovascular disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congestive cardiomyopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 32 / 13769 (0.23%) | 46 / 13756 (0.33%) | |
| occurrences causally related to treatment / all | 0 / 33 | 0 / 48 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery stenosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery thrombosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diastolic dysfunction | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dressler's syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extrasystoles | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart alternation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart valve incompetence | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive cardiomyopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive heart disease | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracardiac thrombus | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic cardiomyopathy | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular dysfunction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microvascular coronary artery disease | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve stenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial infarction | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 31 / 13769 (0.23%) | 31 / 13756 (0.23%) | |
| occurrences causally related to treatment / all | 1 / 31 | 1 / 31 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 26 / 13769 (0.19%) | 21 / 13756 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial necrosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocarditis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prinzmetal angina | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulseless electrical activity | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhythm idioventricular | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Silent myocardial infarction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus arrest | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |
| subjects affected / exposed | 17 / 13769 (0.12%) | 18 / 13756 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular tachycardia | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 9 / 13769 (0.07%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachycardia | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Torsade de pointes | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 12 / 13769 (0.09%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular hypertrophy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachyarrhythmia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachycardia | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 23 / 13769 (0.17%) | 27 / 13756 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 30 | 0 / 33 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amnesia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amputation stump pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amyotrophic lateral sclerosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphasia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Apraxia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arachnoid cyst | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ataxia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Balance disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal ganglia infarction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basilar artery aneurysm | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basilar artery stenosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid arteriosclerosis | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery disease | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 37 / 13769 (0.27%) | 39 / 13756 (0.28%) | |
| occurrences causally related to treatment / all | 2 / 39 | 0 / 43 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar ataxia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar infarction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral arteriosclerosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral artery occlusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral artery stenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral atrophy | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haematoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral infarction | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral thrombosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral vasoconstriction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 25 / 13769 (0.18%) | 21 / 13756 (0.15%) | |
| occurrences causally related to treatment / all | 1 / 26 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular disorder | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular insufficiency | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical cord compression | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical myelopathy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical radiculopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicobrachial syndrome | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicogenic headache | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complex partial seizures | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia Alzheimer's type | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Demyelinating polyneuropathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic neuropathy | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 15 / 13769 (0.11%) | 19 / 13756 (0.14%) | |
| occurrences causally related to treatment / all | 1 / 15 | 0 / 20 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness postural | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysarthria | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dystonia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalitis autoimmune | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |

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|---|-------------------|--------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paralysis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised tonic-clonic seizure | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Guillain-Barre syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 17 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiplegic migraine | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocephalus | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive encephalopathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertonia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic coma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic encephalopathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic unconsciousness | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IIIrd nerve paralysis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial aneurysm | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial mass | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic cerebral infarction | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lacunar infarction | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lacunar stroke | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lethargy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar radiculopathy | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbosacral radiculopathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meralgia paraesthetica | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine with aura | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monoparesis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Motor neurone disease | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve compression | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuralgia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuritis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroglycopenia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuromuscular pain | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraparesis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paresis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinson's disease | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinsonism | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Partial seizures | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral motor neuropathy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peroneal nerve palsy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Petit mal epilepsy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy idiopathic progressive | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postictal state | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudoradicular syndrome | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychomotor hyperactivity | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Quadriplegia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radicular syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiculopathy | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retrograde amnesia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 14 / 13769 (0.10%) | 10 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sedation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 8 / 13769 (0.06%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Speech disorder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal claudication | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord compression | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stroke in evolution | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural effusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 63 / 13769 (0.46%) | 56 / 13756 (0.41%) | |
| occurrences causally related to treatment / all | 2 / 64 | 0 / 59 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tarsal tunnel syndrome | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tension headache | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic outlet syndrome | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic encephalopathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient global amnesia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 42 / 13769 (0.31%) | 36 / 13756 (0.26%) | |
| occurrences causally related to treatment / all | 1 / 43 | 0 / 36 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Unresponsive to stimuli | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular encephalopathy | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral artery occlusion | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar insufficiency | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo CNS origin | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual field defect | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord paralysis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 27 / 13769 (0.20%) | 27 / 13756 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 28 | 0 / 27 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia of chronic disease | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulopathy | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypochromic anaemia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 3 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy mediastinal | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microcytic anaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normochromic normocytic anaemia | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pernicious anaemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polycythaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spleen disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Acute vestibular syndrome | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness unilateral | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inner ear inflammation | | | |

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|---|-------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniere's disease | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otorrhoea | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden hearing loss | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tinnitus | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular ischaemia | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blepharochalasis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract | | | |
| subjects affected / exposed | 15 / 13769 (0.11%) | 22 / 13756 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract nuclear | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dacryoadenitis acquired | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic retinopathy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ectropion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eyelid ptosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glaucoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iridocyclitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular degeneration | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular fibrosis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ocular myasthenia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmoplegia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pterygium | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal artery occlusion | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal artery thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal detachment | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal tear | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal vascular disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal vein thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strabismus | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uveitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual acuity reduced | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal distension | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 12 / 13769 (0.09%) | 19 / 13756 (0.14%) | |
| occurrences causally related to treatment / all | 1 / 13 | 3 / 22 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 12 / 13769 (0.09%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholic pancreatitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fissure | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fistula | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal incontinence | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic ulcer perforation | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic gastritis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coeliac artery stenosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic fistula | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiplonic appendagitis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erosive oesophagitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faecaloma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food poisoning | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cyst | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer perforation | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 19 / 13769 (0.14%) | 17 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis alcoholic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis haemorrhagic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroduodenal haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroduodenitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal angiodysplasia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal angiodysplasia haemorrhagic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 27 / 13769 (0.20%) | 16 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 27 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal polyp haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal ulcer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 14 / 13769 (0.10%) | 15 / 13756 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 14 | 1 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic erosive gastritis | | | |

| | | |
|---|-------------------|--------------------|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Haemorrhoidal haemorrhage | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 5 / 13756 (0.04%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Haemorrhoids | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 10 / 13756 (0.07%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 10 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Haemorrhoids thrombosed | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Hernial eventration | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Hiatus hernia | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 3 / 13756 (0.02%) |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Ileus | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 7 / 13756 (0.05%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Ileus paralytic | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Impaired gastric emptying | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated inguinal hernia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated umbilical hernia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory bowel disease | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 32 / 13769 (0.23%) | 22 / 13756 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 34 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal dilatation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal fistula | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal ischaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal polyp | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal prolapse | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal fluid collection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haematoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intussusception | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Irritable bowel syndrome | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine perforation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine polyp | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 16 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukoplakia oral | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mallory-Weiss syndrome | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mechanical ileus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric arterial occlusion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric artery stenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric artery thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric vein thrombosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Odynophagia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal achalasia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal food impaction | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal obstruction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal spasm | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal stenosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal varices haemorrhage | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis ulcerative | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palatal swelling | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic cyst | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic necrosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic phlegmon | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic pseudocyst | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 10 / 13769 (0.07%) | 16 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 1 / 10 | 1 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 14 / 13769 (0.10%) | 22 / 13756 (0.16%) | |
| occurrences causally related to treatment / all | 1 / 16 | 5 / 28 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis necrotising | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatolithiasis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periodontal disease | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritoneal haematoma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal polyp | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reflux gastritis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retching | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal fibrosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haematoma | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland enlargement | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestine ulcer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strangulated umbilical hernia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress ulcer | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis mesenteric vessel | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue cyst | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue oedema | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth disorder | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth impacted | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 14 / 13756 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 13 / 13769 (0.09%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 13 | 1 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varices oesophageal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Volvulus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 10 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermal cyst | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis exfoliative | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatomyositis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug eruption | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dry skin | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema nummular | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Excessive granulation tissue | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Excessive skin | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Henoch-Schonlein purpura | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lichen myxoedematosus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lichen planus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papulopustular rosacea | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pemphigoid | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus generalised | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriasis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scar pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin exfoliation | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin ulcer | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stasis dermatitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous emphysema | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Swelling face | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urticaria | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 64 / 13769 (0.46%) | 64 / 13756 (0.47%) | |
| occurrences causally related to treatment / all | 3 / 69 | 0 / 66 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute prerenal failure | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Azotaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder dilatation | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder diverticulum | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neck obstruction | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder obstruction | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder outlet obstruction | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder spasm | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder tamponade | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus bladder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urethral | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urinary | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 17 / 13769 (0.12%) | 15 / 13756 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 17 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis haemorrhagic | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic nephropathy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End stage renal disease | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis chronic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis membranous | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |
| subjects affected / exposed | 17 / 13769 (0.12%) | 12 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage urinary tract | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 29 / 13756 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 16 | 1 / 31 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy toxic | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurogenic bladder | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nocturia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive uropathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prerenal failure | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelocaliectasis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal artery stenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst haemorrhage | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal infarct | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal mass | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal pain | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress urinary incontinence | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric rupture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric stenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary incontinence | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 14 / 13769 (0.10%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinoma | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal mass | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basedow's disease | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Goitre | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperparathyroidism | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperparathyroidism primary | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaldosteronism | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inappropriate antidiuretic hormone secretion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid mass | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 18 / 13756 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 16 | 1 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 11 / 13769 (0.08%) | 13 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropathy | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 30 / 13769 (0.22%) | 30 / 13756 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 32 | 0 / 31 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone deformity | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone pain | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical spinal stenosis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis pyrophosphate | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondropathy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costochondritis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic amyotrophy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dupuytren's contracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enthesopathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exostosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exostosis of jaw | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facet joint syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoroacetabular impingement | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibromyalgia | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot deformity | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture nonunion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gouty arthritis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin pain | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc displacement | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 22 / 13769 (0.16%) | 24 / 13756 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 23 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaw cyst | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint adhesion | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint effusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint instability | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint range of motion decreased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb discomfort | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 21 / 13769 (0.15%) | 17 / 13756 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 20 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mobility decreased | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monarthrititis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 49 / 13769 (0.36%) | 37 / 13756 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 54 | 1 / 40 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal stiffness | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myalgia | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 4 / 8 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myalgia intercostal | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myofascitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myositis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck pain | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathic arthropathy | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodal osteoarthritis | | | |

| | | | |
|---|--------------------|---------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 91 / 13769 (0.66%) | 100 / 13756 (0.73%) | |
| occurrences causally related to treatment / all | 1 / 93 | 0 / 109 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondritis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondrosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteolysis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoporosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoporotic fracture | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in jaw | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patellofemoral pain syndrome | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pathological fracture | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periarthritis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyarthritis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyositis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudarthrosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 3 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seronegative arthritis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column stenosis | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal instability | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 9 / 13769 (0.07%) | 12 / 13756 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal pain | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondyloarthropathy | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolysis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sympathetic posterior cervical syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Symphysiolysis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovial cyst | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon necrosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendonitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trigger finger | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral foraminal stenosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral osteophyte | | | |

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|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal sepsis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess bacterial | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess limb | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess of eyelid | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess of salivary gland | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess soft tissue | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amoebic dysentery | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fistula infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendiceal abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 20 / 13769 (0.15%) | 14 / 13756 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 20 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis perforated | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteritis infective | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial pericarditis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial prostatitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial pyelonephritis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial sepsis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteroides bacteraemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Beta haemolytic streptococcal infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast abscess | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 17 / 13769 (0.12%) | 30 / 13756 (0.22%) | |
| occurrences causally related to treatment / all | 1 / 17 | 1 / 30 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis bacterial | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burkholderia cepacia complex infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burkholderia pseudomallei infection | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis infective | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbuncle | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter site infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 39 / 13769 (0.28%) | 28 / 13756 (0.20%) | |
| occurrences causally related to treatment / all | 1 / 43 | 0 / 28 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis gangrenous | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis infective | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic hepatitis B | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Creutzfeldt-Jakob disease | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis escherichia | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dengue fever | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related sepsis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot infection | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gangrene | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 26 / 13756 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 29 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis intestinal haemorrhagic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema infected | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolic pneumonia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Empyema | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalitis viral | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis bacterial | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis haemophilus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endophthalmitis | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis infectious | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterobacter bacteraemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterococcal sepsis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiglottitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 19 / 13756 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipeloid | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia sepsis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fungal peritonitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Furuncle | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder empyema | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |

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|---|--------------------|--------------------|
| subjects affected / exposed | 6 / 13769 (0.04%) | 12 / 13756 (0.09%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 17 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastritis viral | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis | | |
| subjects affected / exposed | 19 / 13769 (0.14%) | 14 / 13756 (0.10%) |
| occurrences causally related to treatment / all | 0 / 20 | 0 / 14 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis bacterial | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis clostridial | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis salmonella | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gingival abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| H1N1 influenza | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helicobacter infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis A | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis B | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis C | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis E | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected bite | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected cyst | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected skin ulcer | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection in an immunocompromised host | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious colitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious pleural effusion | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective exacerbation of chronic obstructive airways disease | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective tenosynovitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 9 / 13769 (0.07%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral discitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 14 / 13769 (0.10%) | 15 / 13756 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 15 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung abscess | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infection | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastoiditis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis bacterial | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis pneumococcal | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle abscess | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotising fasciitis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurosyphilis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenic infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nosocomial infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmic herpes zoster | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 18 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis acute | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis chronic | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis externa | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis externa bacterial | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreas infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paronychia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parotitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perineal abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periodontitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirectal abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal abscess | | | |

| | | | |
|---|---------------------|---------------------|--|
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumococcal sepsis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 147 / 13769 (1.07%) | 152 / 13756 (1.10%) | |
| occurrences causally related to treatment / all | 1 / 154 | 1 / 162 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia adenoviral | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 18 / 13769 (0.13%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia legionella | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia pneumococcal | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia staphylococcal | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural infection | | | |
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural pneumonia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural sepsis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudomembranous colitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoas abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis chronic | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyonephrosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 8 / 13769 (0.06%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection bacterial | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhinovirus infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salmonellosis | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salpingitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 21 / 13769 (0.15%) | 31 / 13756 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 22 | 0 / 32 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 9 / 13756 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin bacterial infection | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin infection | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spermatic cord funiculitis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal abscess | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal sepsis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tick-borne viral encephalitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth abscess | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheitis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculosis | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection bacterial | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteritis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 41 / 13769 (0.30%) | 37 / 13756 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 48 | 0 / 42 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 7 / 13769 (0.05%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 12 / 13769 (0.09%) | 15 / 13756 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular neuronitis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 4 / 13769 (0.03%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral myocarditis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral pericarditis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval abscess | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound abscess | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection bacterial | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection staphylococcal | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound sepsis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Abnormal loss of weight | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cachexia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 16 / 13769 (0.12%) | 18 / 13756 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 61 / 13769 (0.44%) | 56 / 13756 (0.41%) | |
| occurrences causally related to treatment / all | 2 / 71 | 3 / 60 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 10 / 13769 (0.07%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 10 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic metabolic decompensation | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 3 / 13756 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 3 / 13769 (0.02%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid retention | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glucose tolerance impaired | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gout | | | |
| subjects affected / exposed | 6 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperammonaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 8 / 13769 (0.06%) | 8 / 13756 (0.06%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperinsulinaemic hypoglycaemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 10 / 13769 (0.07%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperosmolar hyperglycaemic state | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 17 / 13769 (0.12%) | 11 / 13756 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia unawareness | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 13769 (0.04%) | 7 / 13756 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 5 / 13769 (0.04%) | 5 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovitaminosis | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ketoacidosis | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 2 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 2 / 13769 (0.01%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obesity | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 3 / 13769 (0.02%) | 6 / 13756 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 1 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 13769 (0.00%) | 1 / 13756 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 12 / 13769 (0.09%) | 4 / 13756 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 12 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 1 / 13769 (0.01%) | 0 / 13756 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Evolocumab | Placebo | |
|---|-----------------------|-----------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3500 / 13769 (25.42%) | 3438 / 13756 (24.99%) | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 1069 / 13769 (7.76%) | 1157 / 13756 (8.41%) | |
| occurrences (all) | 1193 | 1315 | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1067 / 13769 (7.75%) | 1021 / 13756 (7.42%) | |
| occurrences (all) | 1364 | 1260 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 692 / 13769 (5.03%) | 649 / 13756 (4.72%) | |
| occurrences (all) | 807 | 788 | |
| Metabolism and nutrition disorders | | | |

| | | | |
|-----------------------------|-------------------------|-------------------------|--|
| Diabetes mellitus | | | |
| subjects affected / exposed | 1156 / 13769 (8.40%) | 1096 / 13756 (7.97%) | |
| occurrences (all) | 1255 | 1200 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 05 September 2012 | <ul style="list-style-type: none">• add testing for prior or existing Hepatitis C virus (HCV) infection in high risk individuals and monitoring of viral load in those who show evidence thereof• add the exclusion of family history of hereditary muscular disorders• add instruction that investigators will ask study subjects to promptly report muscle pain, cramps, or weakness especially if accompanied by malaise or fever and provide further detail regarding stopping rules for atorvastatin and investigational product in case of elevated creatine kinase levels• provide guidance regarding actions to take if the subject requires treatment with a strong CYP3A4 inhibitor while on study• add baseline electrocardiogram (ECG) in triplicate for all subjects, not just at sites provided with centralized ECG services equipment• add a description of composition and role of the Clinical Events Committee (CEC)• add serum pregnancy testing at the randomization visit (day 1) for women of childbearing potential• add ezetimibe use at baseline to covariates |
| 24 September 2012 | <ul style="list-style-type: none">• add study name FOURIER• add phase 3 formulation information for IP and introduce the prefilled autoinjector/pen for administration of the IP• modify Schedule of Assessments for reduced visit frequency and IP administration by autoinjector/pen at locations external to study center• prolong the time investigators are not to perform non-protocol testing of blinded analytes to 12 weeks after last IP administration or end of study, whichever is later• provide more specificity about adjudicated clinical events• add information about the study Executive Committee and Lipid Monitoring Committee• add reporting requirements for product/device complaints• replace routine visits with administration of IP external to the study center• extend maximal duration of screening from 12 to 15 weeks• add HCV testing at enrollment and evaluation of viral load during the study, if positive, for subjects with a history of HCV infection• increase planned sites to 1000• clarify definition of metabolic syndrome in inclusion criteria• add homozygous familial hypercholesterolemia and LDL or plasma apheresis within 12 months to exclusions• add Israel and Australasia• clarify that all cause death, MI, stroke, revascularization, hospitalization for unstable angina, hospitalization for HF, and TIA are not considered SAEs in this study, but will be handled as efficacy endpoints• clarify that Amgen will review all fatal endpoints to evaluate whether the cause of death is due to a SAE that is a specific concern for a protein therapeutic or which may be individually informative. If detected, Amgen will notify the investigator to submit a SAE eCRF within 24 hours of Amgen's notification.• change time to first hospitalization for worsening HF secondary endpoint to composite endpoint of time to CV death or hospitalization for HF• add secondary endpoint of time to ischemic fatal or non-fatal stroke or TIA• modify lab assessment schedule, including collection biomarker samples |
| 12 December 2012 | <ul style="list-style-type: none">• clarify that the reporting process for potential endpoints and the information collected corresponds to the requirements and the information collected for serious adverse events• clarify that the physical exam should include a neurological exam• increase the upper age limit to 85 years from 80 years• add notification of the investigator if triglycerides are > 1000 mg/dL• add collection of the reason why subjects switch investigational product administration regimen• add alert threshold for elevated triglycerides• add measurement of urine microalbumin at week 48 and end of study |

| | |
|-------------------|--|
| 16 July 2013 | <ul style="list-style-type: none"> •allow statins other than atorvastatin for background lipid lowering therapy •redefine the acceptable lipid therapy, including changes in allowed lipid therapy other than statins •include symptomatic peripheral arterial disease as evidence of cardiovascular disease • minor modifications of the risk factors for eligibility • add the automated mini doser (also referred to as the 3.5 mL personal injector) to the investigational product administration devices • increase the number of study centers • allow QM dosing from initiation of IP administration • add option of an informed consent for screening and lipid therapy titration only • update the section on withdrawal from treatment • update sections on adverse event and serious adverse event reporting |
| 28 August 2014 | <ul style="list-style-type: none"> • increase enrollment from approximately 22,500 to up to approximately 27,500 randomized subjects • update key sponsor contact information • add the product name evolocumab |
| 29 September 2015 | <ul style="list-style-type: none"> • add the major components of the primary objective and endpoint as separate secondary objectives and endpoints • revise statistical testing to account for the additional secondary endpoints • add adjudication of new onset diabetes. • revise section on prohibited treatments during the study to account for recent results of another trial (IMPROVE-IT) and enable addition of ezetimibe in subjects experiencing an acute coronary syndrome during the study. Ezetimibe was not prohibited prior to this amendment, as long as subjects were on stable doses at the time of randomization. • add HbA1c to blood draws at week 24 and Q24W visit to assist detection of new onset diabetes. • revise end-of-study procedures to enable more flexibility for sites to schedule end-of-study visits and add a safety contact at 30 days after last administration of IP if the end-of-study visit is less than 30 days after last IP. • add text for the collection of vital status information. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported