



Clinical trial results:

A RANDOMIZED, PLACEBO CONTROLLED CLINICAL TRIAL TO EVALUATE CARDIOVASCULAR OUTCOMES AFTER TREATMENT WITH EXENATIDE ONCE WEEKLY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

Summary

| | |
|--------------------------|--|
| EudraCT number | 2010-021069-63 |
| Trial protocol | DE LT LV AT GB CZ SK HU BG IT BE NL ES |
| Global end of trial date | 24 April 2017 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 23 May 2018 |
| First version publication date | 23 May 2018 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | D5551C00003 |
|-----------------------|-------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | AstraZeneca Inc. |
| Sponsor organisation address | 950 Wind River Ln, Gaithersburg, United States, MD, 20878 |
| Public contact | Peter Ohman, AstraZeneca Inc., 1 (301)398-0120, Peter.Ohman@astrazeneca.com |
| Scientific contact | Peter Ohman, AstraZeneca Inc., 1 (301)398-0120, Peter.Ohman@astrazeneca.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 | 31 March 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 21 April 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 April 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To compare the impact of including EQW in addition to usual care vs. usual care without EQW on major CV outcomes as measured by the primary CV composite endpoint of CV-related death, nonfatal myocardial infarction (MI), or nonfatal stroke.

Protection of trial subjects:

Treated with routine care.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 10 June 2010 |
| 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 | Austria: 278 |
| Country: Number of subjects enrolled | Belgium: 28 |
| Country: Number of subjects enrolled | Bulgaria: 378 |
| Country: Number of subjects enrolled | Czech Republic: 138 |
| Country: Number of subjects enrolled | Germany: 982 |
| Country: Number of subjects enrolled | Hungary: 1047 |
| Country: Number of subjects enrolled | Israel: 441 |
| Country: Number of subjects enrolled | Italy: 82 |
| Country: Number of subjects enrolled | Latvia: 228 |
| Country: Number of subjects enrolled | Lithuania: 240 |
| Country: Number of subjects enrolled | Netherlands: 89 |
| Country: Number of subjects enrolled | Poland: 412 |
| Country: Number of subjects enrolled | Romania: 362 |
| Country: Number of subjects enrolled | Russian Federation: 207 |
| Country: Number of subjects enrolled | Slovakia: 397 |
| Country: Number of subjects enrolled | South Africa: 306 |
| Country: Number of subjects enrolled | Spain: 220 |
| Country: Number of subjects enrolled | Ukraine: 606 |
| Country: Number of subjects enrolled | United Kingdom: 347 |
| Country: Number of subjects enrolled | Canada: 544 |
| Country: Number of subjects enrolled | United States: 3164 |

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Argentina: 189 |
| Country: Number of subjects enrolled | Brazil: 1728 |
| Country: Number of subjects enrolled | Chile: 134 |
| Country: Number of subjects enrolled | Colombia: 275 |
| Country: Number of subjects enrolled | Mexico: 401 |
| Country: Number of subjects enrolled | Australia: 186 |
| Country: Number of subjects enrolled | China: 300 |
| Country: Number of subjects enrolled | Hong Kong: 158 |
| Country: Number of subjects enrolled | Malaysia: 124 |
| Country: Number of subjects enrolled | New Zealand: 151 |
| Country: Number of subjects enrolled | Philippines: 254 |
| Country: Number of subjects enrolled | Korea, Republic of: 215 |
| Country: Number of subjects enrolled | Taiwan: 122 |
| Country: Number of subjects enrolled | Thailand: 19 |
| Worldwide total number of subjects | 14752 |
| EEA total number of subjects | 5228 |

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) | 8813 |
| From 65 to 84 years | 5888 |
| 85 years and over | 51 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Informed consent, and if feasible, randomization will occur at the initial trial visit for patients satisfying all inclusion and exclusion criteria. 15185 pts were enrolled at screening/randomization visit and 433 failed screening criteria.

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 | Investigator, Data analyst, Subject |

Arms

| | |
|------------------------------|-----------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Exenatide once weekly |

Arm description:

Exenatide 2mg once weekly subcutaneous injections

| | |
|--|----------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Exenatide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

2 mg one time per week, injection

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Matching placebo subcutaneous injections

| | |
|--|----------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

one time per week, injection

| Number of subjects in period 1 | Exenatide once weekly | Placebo |
|---------------------------------------|-----------------------|---------|
| Started | 7356 | 7396 |
| Completed | 7094 | 7093 |
| Not completed | 262 | 303 |
| Consent withdrawn by subject | 223 | 270 |
| Lost to follow-up | 39 | 33 |

Baseline characteristics

Reporting groups

| | |
|---|-----------------------|
| Reporting group title | Exenatide once weekly |
| Reporting group description: | |
| Exenatide 2mg once weekly subcutaneous injections | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Matching placebo subcutaneous injections | |

| Reporting group values | Exenatide once weekly | Placebo | Total |
|--|-----------------------|---------|-------|
| Number of subjects | 7356 | 7396 | 14752 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 4392 | 4421 | 8813 |
| From 65-84 years | 2939 | 2949 | 5888 |
| 85 years and over | 25 | 26 | 51 |
| Age Continuous | | | |
| Age at enrollment | | | |
| Units: Years | | | |
| arithmetic mean | 61.8 | 61.9 | |
| standard deviation | ± 9.4 | ± 9.4 | - |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| MALE | 4562 | 4587 | 9149 |
| FEMALE | 2794 | 2809 | 5603 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| WHITE | 5554 | 5621 | 11175 |
| BLACK OR AFRICAN AMERICAN | 442 | 436 | 878 |
| ASIAN | 725 | 727 | 1452 |
| INDIAN (AMERICAN) OR ALASKA NATIVE | 38 | 35 | 73 |
| NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER | 18 | 17 | 35 |
| HISPANIC | 577 | 557 | 1134 |
| MISSING | 2 | 3 | 5 |
| Region of Enrollment | | | |
| Units: Subjects | | | |
| ASIA PACIFIC | 769 | 760 | 1529 |
| EUROPE | 3389 | 3399 | 6788 |
| LATIN AMERICA | 1364 | 1363 | 2727 |

| | | | |
|--|------|------|-------|
| NORTH AMERICA | 1834 | 1874 | 3708 |
| Prior CV Event | | | |
| Patient had prior cardiovascular event or not at randomization | | | |
| Units: Subjects | | | |
| Has Prior CV Event | 5394 | 5388 | 10782 |
| No Prior CV Event | 1962 | 2008 | 3970 |

End points

End points reporting groups

| | |
|---|-----------------------|
| Reporting group title | Exenatide once weekly |
| Reporting group description: | |
| Exenatide 2mg once weekly subcutaneous injections | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Matching placebo subcutaneous injections | |

Primary: Primary Efficacy Outcome MACE Events

| | |
|---|--------------------------------------|
| End point title | Primary Efficacy Outcome MACE Events |
| End point description: | |
| The primary efficacy outcome variable is defined as the composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke | |
| End point type | Primary |
| End point timeframe: | |
| Time to first event. Information collected during study period (anticipated to be up to 7.5 years). | |

| End point values | Exenatide once weekly | Placebo | | |
|---|-----------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Number of patients who had a MACE event | 839 | 905 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Cox Regression |
| Comparison groups | Exenatide once weekly v Placebo |
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.061 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.832 |
| upper limit | 1.004 |

Primary: Primary Safety Outcome MACE Events

| | |
|-----------------|------------------------------------|
| End point title | Primary Safety Outcome MACE Events |
|-----------------|------------------------------------|

End point description:

The primary safety outcome variable is defined as the composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

| End point values | Exenatide once weekly | Placebo | | |
|---|-----------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Number of patients who had a MACE event | 839 | 905 | | |

Statistical analyses

| Statistical analysis title | Cox Regression |
|---|---------------------------------|
| Comparison groups | Exenatide once weekly v Placebo |
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.001 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.832 |
| upper limit | 1.004 |

Secondary: Secondary Efficacy Outcome All-Cause Mortality

| | |
|-----------------|--|
| End point title | Secondary Efficacy Outcome All-Cause Mortality |
|-----------------|--|

End point description:

The secondary efficacy outcome variable is defined as the all-cause mortality (deaths).

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

End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

| End point values | Exenatide once weekly | Placebo | | |
|-----------------------------|-----------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Number of patients who died | 507 | 584 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Cox Regression |
| Comparison groups | Exenatide once weekly v Placebo |
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.016 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.86 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.77 |
| upper limit | 0.97 |

Secondary: Secondary Efficacy Outcome CV Death

| | |
|---|-------------------------------------|
| End point title | Secondary Efficacy Outcome CV Death |
| End point description: | |
| Component of the primary efficacy outcome: cardiovascular death. | |
| End point type | Secondary |
| End point timeframe: | |
| Time to first event. Information collected during study period (anticipated to be up to 7.5 years). | |

| End point values | Exenatide once weekly | Placebo | | |
|-------------------------------------|-----------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Number of patients who had CV death | 340 | 383 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Cox Regression |
| Comparison groups | Exenatide once weekly v Placebo |
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.096 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.76 |
| upper limit | 1.02 |

Secondary: Secondary Efficacy Outcome MI

| | |
|---|-------------------------------|
| End point title | Secondary Efficacy Outcome MI |
| End point description: | |
| Component of primary efficacy outcome: fatal or non-fatal MI. | |
| End point type | Secondary |
| End point timeframe: | |
| Time to first event. Information collected during study period (anticipated to be up to 7.5 years). | |

| | | | | |
|--|-----------------------|-----------------|--|--|
| End point values | Exenatide once weekly | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Number of patients who had an MI event | 483 | 493 | | |

Statistical analyses

| | |
|-----------------------------------|---------------------------------|
| Statistical analysis title | Cox Regression |
| Comparison groups | Exenatide once weekly v Placebo |

| | |
|---|-------------------|
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.622 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.97 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.1 |

Secondary: Secondary Efficacy Outcome Stroke

| | |
|---|-----------------------------------|
| End point title | Secondary Efficacy Outcome Stroke |
| End point description: | |
| Component of primary efficacy outcome: fatal or non-fatal stroke. | |
| End point type | Secondary |
| End point timeframe: | |
| Time to first event. Information collected during study period (anticipated to be up to 7.5 years). | |

| End point values | Exenatide once weekly | Placebo | | |
|-----------------------------------|-----------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Number of patients who had stroke | 187 | 218 | | |

Statistical analyses

| | |
|---|---------------------------------|
| Statistical analysis title | Cox Regression |
| Comparison groups | Exenatide once weekly v Placebo |
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.095 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.85 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 1.03 |

Secondary: Secondary Efficacy Outcome Hospitalization for ACS

| | |
|-----------------|--|
| End point title | Secondary Efficacy Outcome Hospitalization for ACS |
|-----------------|--|

End point description:

The secondary efficacy outcome variable is defined as hospitalization for acute coronary syndrome.

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

End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

| End point values | Exenatide once weekly | Placebo | | |
|--|-----------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Num of pts with hospitalization due to ACS | 602 | 570 | | |

Statistical analyses

| Statistical analysis title | Cox Regression |
|---|---------------------------------|
| Comparison groups | Exenatide once weekly v Placebo |
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.402 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.94 |
| upper limit | 1.18 |

Secondary: Secondary Efficacy Outcome Hospitalization for HF

| | |
|-----------------|---|
| End point title | Secondary Efficacy Outcome Hospitalization for HF |
|-----------------|---|

End point description:

The secondary efficacy outcome variable is defined as hospitalization for heart failure.

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

End point timeframe:

Time to first event. Information collected during study period (anticipated to be up to 7.5 years).

| End point values | Exenatide once weekly | Placebo | | |
|--|-----------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7356 | 7396 | | |
| Units: Participants | | | | |
| Number of patients who were hospitalization for HF | 219 | 231 | | |

Statistical analyses

| Statistical analysis title | Cox Regression |
|---|---------------------------------|
| Comparison groups | Exenatide once weekly v Placebo |
| Number of subjects included in analysis | 14752 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.485 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.78 |
| upper limit | 1.13 |

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From first dose of study drug until last study visit

Adverse event reporting additional description:

Only serious adverse event is collected for this study.

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

Dictionary used

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

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

Reporting groups

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

Reporting group description: -

| | |
|-----------------------|----------|
| Reporting group title | EQW 2 mg |
|-----------------------|----------|

Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Only SAE are collected in this study.

| Serious adverse events | Placebo | EQW 2 mg | |
|---|----------------------|----------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1222 / 7372 (16.58%) | 1234 / 7344 (16.80%) | |
| number of deaths (all causes) | 584 | 507 | |
| number of deaths resulting from adverse events | 87 | 70 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| ACTH-producing pituitary tumour | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Adenocarcinoma gastric | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of appendix | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 9 / 7372 (0.12%) | 12 / 7344 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Adenoma benign | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal adenoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal cancer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiosarcoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendix cancer | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| B-cell lymphoma | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 25 / 7372 (0.34%) | 25 / 7344 (0.34%) | |
| occurrences causally related to treatment / all | 0 / 33 | 0 / 42 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basosquamous carcinoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign gastric neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign laryngeal neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign lung neoplasm | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of thyroid gland | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign oesophageal neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign ovarian tumour | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign salivary gland neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign small intestinal neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct cancer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 9 / 7344 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Bladder cancer recurrent | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer stage 0, with cancer in situ | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder papilloma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma recurrent | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bowen's disease | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm malignant | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Breast cancer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer female | | | |
| subjects affected / exposed | 14 / 7372 (0.19%) | 16 / 7344 (0.22%) | |
| occurrences causally related to treatment / all | 1 / 14 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Breast cancer male | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer metastatic | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Breast neoplasm | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial carcinoma | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid body tumour | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemangioma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix carcinoma recurrent | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangiocarcinoma | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Choroid melanoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Clear cell endometrial carcinoma | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clear cell renal cell carcinoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon adenoma | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 16 / 7344 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 16 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Colon cancer stage I | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Colorectal adenocarcinoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Colorectal cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Desmoplastic melanoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diffuse large B-cell lymphoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ear neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial adenocarcinoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial adenoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial cancer | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epithelioid mesothelioma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Essential thrombocythaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibroma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibrosarcoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gallbladder cancer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric adenoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Gastric neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastrointestinal carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stromal tumour | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal submucosal tumour | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Glioblastoma multiforme | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Haemangioblastoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemangioma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hairy cell leukaemia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic adenoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Hepatic cancer metastatic | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Hodgkin's disease | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal cancer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal squamous cell carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip neoplasm | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipoma | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Lung adenocarcinoma metastatic | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung cancer metastatic | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 4 | |
| Lung carcinoma cell type unspecified stage IV | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 12 / 7372 (0.16%) | 12 / 7344 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 9 | 0 / 7 | |
| Lung squamous cell carcinoma metastatic | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lymphoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant anorectal neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant ascites | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 8 / 7344 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant melanoma in situ | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 unknown primary site | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant pleural effusion | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mantle cell lymphoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melanocytic naevus | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesothelioma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Mesothelioma malignant | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to adrenals | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to liver | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to lymph nodes | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastasis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastatic neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic renal cell carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Metastatic uterine cancer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myeloproliferative neoplasm | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Nasal sinus cancer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm malignant | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Neoplasm prostate | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Neuroendocrine carcinoma of the skin | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine tumour | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Non-small cell lung cancer metastatic | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Non-small cell lung cancer stage IV | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Oesophageal adenocarcinoma | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal cancer metastatic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal carcinoma | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Oropharyngeal cancer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cancer | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ovarian neoplasm | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 15 / 7372 (0.20%) | 15 / 7344 (0.20%) | |
| occurrences causally related to treatment / all | 2 / 15 | 1 / 15 | |
| deaths causally related to treatment / all | 3 / 9 | 2 / 10 | |
| Pancreatic neuroendocrine tumour | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary thyroid cancer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraproteinaemia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Parathyroid tumour benign | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Penile cancer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral T-cell lymphoma unspecified | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pituitary tumour benign | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 5 / 7372 (0.07%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 26 / 7372 (0.35%) | 20 / 7344 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 20 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer recurrent | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Prostate cancer stage I | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal neoplasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectosigmoid cancer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal oncocytoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory papilloma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal melanoma | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Salivary gland cancer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seborrhoeic keratosis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinonasal papilloma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin cancer | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Small intestine carcinoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Spinal meningioma benign | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 13 / 7372 (0.18%) | 12 / 7344 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Squamous cell carcinoma of head and neck | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 8 / 7372 (0.11%) | 7 / 7344 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the hypopharynx | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Squamous cell carcinoma of the oral cavity | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the tongue | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid cancer | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 14 / 7344 (0.19%) | |
| occurrences causally related to treatment / all | 1 / 7 | 2 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|------------------|------------------|--|
| Tongue neoplasm malignant stage unspecified | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsil cancer metastatic | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma urethra | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 3 / 7372 (0.04%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval cancer | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Xanthogranuloma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |

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|---|------------------|------------------|--|
| Arterial rupture | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bleeding varicose vein | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 8 / 7344 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphocele | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post thrombotic syndrome | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Temporal arteritis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicose vein | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Cephalhaematoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cephalo-pelvic disproportion | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pre-eclampsia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Adverse drug reaction | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthenia | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Complication associated with device | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyst | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug interaction | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granuloma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic cyst | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired healing | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired self-care | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injection site inflammation | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 79 / 7372 (1.07%) | 87 / 7344 (1.18%) | |
| occurrences causally related to treatment / all | 0 / 90 | 1 / 104 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 7372 (0.05%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyp | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strangulated hernia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoidosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Alcohol use | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Acquired phimosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrophic vulvovaginitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 11 / 7372 (0.15%) | 9 / 7344 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast mass | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|------------------|------------------|--|
| Cystocele | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymal cyst | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Female genital tract fistula | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genital lesion | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gynaecomastia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Menorrhagia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metrorrhagia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Organic erectile dysfunction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian vein thrombosis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine polyp | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine prolapse | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acquired diaphragmatic eventration | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 10 / 7372 (0.14%) | 8 / 7344 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 10 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Alveolitis allergic | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthmatic crisis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis chronic | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 49 / 7372 (0.66%) | 48 / 7344 (0.65%) | |
| occurrences causally related to treatment / all | 0 / 81 | 0 / 84 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 18 / 7372 (0.24%) | 11 / 7344 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysema | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 7372 (0.05%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiccups | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrothorax | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung disorder | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal septum perforation | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal turbinate hypertrophy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 10 / 7372 (0.14%) | 9 / 7344 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural fibrosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mass | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory acidosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 13 / 7372 (0.18%) | 12 / 7344 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Restrictive pulmonary disease | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 7 / 7344 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stridor | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheal stenosis | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheomalacia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholism | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar disorder | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional state | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |
| subjects affected / exposed | 14 / 7372 (0.19%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression suicidal | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Major depression | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 7 / 7344 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Personality change due to a general medical condition | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic stress disorder | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychogenic seizure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 / 7372 (0.01%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device battery issue | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device dislocation | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device failure | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device loosening | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device malfunction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device occlusion | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patient-device incompatibility | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Acute hepatic failure | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Bile duct stenosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary cirrhosis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary cyst | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic hepatic failure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug-induced liver injury | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder fistula | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder polyp | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Hepatic haematoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic lesion | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic mass | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatomegaly | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatosplenomegaly | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal vein thrombosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Anticoagulation drug level increased | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood calcitonin increased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium decreased | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eosinophil count increased | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HIV test positive | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 / 7372 (0.01%) | 0 / 7344 (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 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 1 / 1 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Accident | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acetabulum fracture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| 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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic ulcer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 11 / 7344 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropod sting | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain contusion | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical vertebral fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Comminuted fracture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complicated fracture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contrast media reaction | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear injury | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural haematoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial bones fracture | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 14 / 7372 (0.19%) | 12 / 7344 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 10 / 7344 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 13 / 7372 (0.18%) | 9 / 7344 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Forearm fracture | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal anastomotic leak | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria traumatic | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic haematoma | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 14 / 7344 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 10 / 7344 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ilium fracture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated incisional hernia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional overdose | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laceration | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple fractures | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple injuries | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Muscle injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle rupture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nail injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 7 / 7372 (0.09%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 7 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patella fracture | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periprosthetic fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirenal haematoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post laminectomy syndrome | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative fever | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative ileus | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative respiratory failure | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative thoracic procedure complication | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound complication | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pneumothorax | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pubis fracture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiation pneumonitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius fracture | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 14 / 7372 (0.19%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scapula fracture | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seroma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin injury | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fractured base | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue injury | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column injury | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord injury cervical | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic injury | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic rupture | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haematoma | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 11 / 7344 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon rupture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal burn | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 8 / 7372 (0.11%) | 8 / 7344 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Traumatic haemothorax | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic liver injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper limb fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 7372 (0.04%) | 7 / 7344 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound dehiscence | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound evisceration | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Arteriovenous malformation | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal arteriovenous malformation | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic arteriovenous malformation | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|------------------|------------------|--|
| Hydrocele | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phimosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rathke's cleft cyst | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sacralisation | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thalassaemia beta | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Angina pectoris | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|------------------|------------------|--|
| Amputation stump pain | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asterixis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autonomic neuropathy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain injury | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrospinal fluid leakage | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical myelopathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical radiculopathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicobrachial syndrome | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicogenic headache | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cognitive disorder | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coma | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Coordination abnormal | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia Alzheimer's type | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Demyelinating polyneuropathy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paralysis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 6 / 7372 (0.08%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paresis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Frontotemporal dementia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised tonic-clonic seizure | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Guillain-Barre syndrome | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocephalus | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotonia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Idiopathic generalised epilepsy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial pressure increased | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar radiculopathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbosacral radiculopathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mixed dementia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple sclerosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myasthenia gravis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelitis transverse | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve compression | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve root compression | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuralgic amyotrophy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuritis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurodegenerative disorder | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normal pressure hydrocephalus | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinsonism | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Partial seizures | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post herpetic neuralgia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post stroke seizure | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Restless legs syndrome | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 10 / 7372 (0.14%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Senile dementia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal claudication | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord compression | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitic myelopathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status epilepticus | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subacute combined cord degeneration | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural hygroma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trigeminal neuralgia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VIth nerve paralysis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular dementia | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular headache | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar insufficiency | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 7372 (0.05%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 26 / 7372 (0.35%) | 15 / 7344 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 31 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Antiphospholipid syndrome | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune haemolytic anaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone marrow disorder | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone marrow oedema | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulopathy | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disseminated intravascular coagulation | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |

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|---|------------------|-------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 11 / 7344 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy mediastinal | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastocytosis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microcytic anaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mixed deafness | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tympanic membrane disorder | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tympanic membrane perforation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular disorder | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blindness unilateral | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diplopia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extraocular muscle disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorder | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye pain | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glaucoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lens dislocation | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular fibrosis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular hole | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular oedema | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Open angle glaucoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal haemorrhage | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulcerative keratitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual impairment | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 7 / 7344 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal incarcerated hernia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal strangulated hernia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fissure | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fistula | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anorectal stenosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anorectal varices | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic gastritis | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diaphragmatic hernia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis haemorrhagic | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocoele | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocutaneous fistula | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epigastric discomfort | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erosive oesophagitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faecaloma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric antral vascular ectasia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric fistula | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric perforation | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric polyps | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer perforation | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric varices haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 12 / 7372 (0.16%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 12 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroduodenal haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorder | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 34 / 7372 (0.46%) | 27 / 7344 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 37 | 1 / 30 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastrointestinal hypomotility | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal inflammation | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal melanosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal obstruction | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 10 | 2 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiatus hernia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired gastric emptying | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory bowel disease | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 9 / 7344 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haematoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haemorrhage | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jejunal perforation | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.01%) | 0 / 7344 (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 / 7372 (0.14%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar hernia | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mallory-Weiss syndrome | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal perforation | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal polyp | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal varices haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral dysaesthesia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oroantral fistula | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic mass | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 22 / 7372 (0.30%) | 37 / 7344 (0.50%) | |
| occurrences causally related to treatment / all | 2 / 24 | 3 / 37 | |
| deaths causally related to treatment / all | 2 / 2 | 0 / 0 | |
| Peptic ulcer | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritoneal haematoma | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal polyp | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectourethral fistula | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haematoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haemorrhage | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal mass | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 8 / 7372 (0.11%) | 7 / 7344 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal perforation | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strangulated umbilical hernia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subileus | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue haemorrhage | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 14 / 7372 (0.19%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 10 / 7372 (0.14%) | 9 / 7344 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 10 | 1 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varices oesophageal | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Actinic keratosis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angioedema | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis bullous | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug eruption | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granuloma skin | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ingrowing nail | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Keloid scar | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lichen planus | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lichenoid keratosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parapsoriasis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prurigo | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash generalised | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stasis dermatitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical haemorrhage | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urticaria | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Azotaemia | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Bladder discomfort | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder mass | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus bladder | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urethral | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urinary | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis chronic | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertonic bladder | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotonic urinary bladder | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 13 / 7372 (0.18%) | 15 / 7344 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrosclerosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive uropathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvi-ureteric obstruction | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 8 / 7344 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (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 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal mass | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress urinary incontinence | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric stenosis | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 10 / 7344 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral haemorrhage | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary bladder polyp | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 7 / 7372 (0.09%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Adrenal mass | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune thyroiditis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cushing's syndrome | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Goitre | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 7 / 7344 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperaldosteronism | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid disorder | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid mass | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic nodular goitre | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 3 / 7372 (0.04%) | 6 / 7344 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthrofibrosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Articular calcification | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 12 / 7372 (0.16%) | 14 / 7344 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical spinal stenosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest wall haematoma | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis pyrophosphate | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costochondritis | | | |
| subjects affected / exposed | 3 / 7372 (0.04%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crystal arthropathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deformity thorax | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exostosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot deformity | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture nonunion | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemarthrosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc compression | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 4 / 7372 (0.05%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 17 / 7372 (0.23%) | 15 / 7344 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc space narrowing | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint effusion | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint instability | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 20 / 7372 (0.27%) | 12 / 7344 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscal degeneration | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monarthrititis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle spasms | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 10 / 7344 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal deformity | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal pain | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 7372 (0.08%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myositis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck pain | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathic arthropathy | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 79 / 7372 (1.07%) | 69 / 7344 (0.94%) | |
| occurrences causally related to treatment / all | 0 / 89 | 0 / 76 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondritis | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondrosis | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 4 / 7372 (0.05%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pathological fracture | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periarthritis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periostitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyarthritits | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatic disorder | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sacroiliitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column stenosis | | | |
| subjects affected / exposed | 10 / 7372 (0.14%) | 4 / 7344 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal disorder | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 11 / 7344 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal pain | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 7372 (0.04%) | 3 / 7344 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondyloarthropathy | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 6 / 7372 (0.08%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovial cyst | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon pain | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral foraminal stenosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral osteophyte | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 0 / 7344 (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 | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic tonsillitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dengue fever | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endophthalmitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiglottitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis E | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster oticus | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective exacerbation of chronic obstructive airways disease | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Keratouveitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudomembranous colitis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular neuronitis | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Acidosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (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 | 8 / 7372 (0.11%) | 10 / 7344 (0.14%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 5 / 7372 (0.07%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid overload | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 7372 (0.03%) | 5 / 7344 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypernatraemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 0 / 7344 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 2 / 7372 (0.03%) | 2 / 7344 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (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 | 2 / 7372 (0.03%) | 8 / 7344 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactic acidosis | | | |
| subjects affected / exposed | 1 / 7372 (0.01%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactose intolerance | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 7372 (0.00%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obesity | | | |
| subjects affected / exposed | 9 / 7372 (0.12%) | 1 / 7344 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Placebo | EQW 2 mg | |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 7372 (0.00%) | 0 / 7344 (0.00%) | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 11 November 2010 | <p>Amylin Pharmaceuticals, Inc., sponsor of the IND in the US and Puerto Rico, transferred clinical sponsor obligations to Eli Lilly and Company for the conduct of the study outside the US, Puerto Rico, and Canada.</p> <p>Monitoring of serum calcitonin throughout the trial was added, specifying collection at baseline, annually, and trial termination.</p> <p>Storage temperatures for the diluent were revised from between 2°C and 27°C to between 2°C and 25°C.</p> <p>Injection site specification was expanded to the thigh and back of the upper arm in addition to the abdomen.</p> <p>Collection of AEs leading to discontinuation was restricted to SAEs.</p> <p>Events of pancreatitis and neoplasia were specified as to be treated as SAEs, collected and reported as ancillary events.</p> <p>The SAC was added to provide operational oversight across all participating institutions.</p> |
| 10 May 2011 | <p>Inclusion criteria were expanded to include patients taking insulin who had been using a stable dose of insulin ($\pm 20\%$ of the scheduled total daily insulin dose), either alone or in combination with a stable dose of metformin for at least 3 months).</p> <p>Exclusion criteria were expanded to restrict patients with a history (≥ 2 episodes) of severe hypoglycemia within 12 months of enrollment.</p> <p>Exclusion criteria were expanded to restrict patients with a personal or family history of medullary thyroid cancer or Multiple Endocrine Neoplasia Type 2 or serum calcitonin level >40 ng/L at baseline.</p> <p>Criterion for discontinuing trial drug was set to ≥ 50 ng/L of serum calcitonin.</p> |
| 23 April 2012 | <p>Inclusion criteria were changed to allow patients with an HbA1c $\geq 6.5\%$ and using insulin, alone or in combination with oral antihyperglycemic medications, to enroll in the study.</p> <p>The requirement for patients to have been on a stable dose of oral antihyperglycemic medication was removed</p> |
| 12 September 2012 | <p>References to sponsorship by Eli Lilly and Company were deleted, and Amylin assumed sole sponsorship of the study.</p> |

| | |
|-----------------|---|
| 25 October 2013 | Based on blinded review of accrued data, the event rate for the primary composite CV endpoint was approximately 2.2 per 100 patient-years, which was less than the anticipated rate of 3.8 per 100 patient-years. To achieve completion of the study within the commitment date of the FDA Post- Marketing Request, a number of measures were taken: The power of the study to achieve the primary objective of superiority of EQW versus PBO with regard to the primary composite CV endpoint was reduced from 90% to 85% resulting in a reduction of the targeted number of events from 1591 to 1360. The total number of patients to be enrolled to achieve the targeted number of events was increased from 9500 to 14000. The proportion of patients enrolled with a prior history of a CV event was increased from 60% to 80% (for newly enrolled patients). Since more than 7000 patients had been enrolled under the 60:40 scheme, it was anticipated that the ratio of patients with prior history of CV event to those with no prior CV event would be approximately 70:30 at study end. It was anticipated that more than 4000 patients (around 30%) without any prior CV history would be enrolled in the study. The minimum follow-up duration of 4 years for a patient was eliminated. The following changes were also made: The secondary hypothesis of non-inferiority of EQW vs PBO regarding the primary composite CV endpoint was updated to a primary safety hypothesis. The end of study procedures was clarified. Clarifications were made to the specifications around withdrawal of consent, lost-to-follow-up procedures, and the follow-up phone call for safety purposes after end-of-study discontinuation of study treatment. Updates to planned interim analyses to match the change in planned total number of events were made as specified in the DSMB charter. Administrative changes, such as requirements for reporting of a potential serious breach of GCP, record retention, source documentation, CRF completion and the CSR were made. |
| 09 March 2016 | The time period for inclusion of primary endpoints was extended past the primary endpoint cut-off date to the trial termination visit. Procedures for handling Clinical Events were changed so that such events would be collected and reported in the same way both pre- and post-cut-off date. An on-treatment (through the last dose of study medication or the trial termination visit, whichever occurred first) analysis of the ITT population was included for the primary and some secondary endpoints as sensitivity analyses. Administrative changes noted the replacement of Professor Robert Califf by Dr. Adrian Felipe Hernandez. Administrative note was made of the fact that Amylin remained the sponsor of the study, but that Amylin was now a wholly-owned subsidiary of AstraZeneca. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Only SAE are collected in this study.

Notes: