



Clinical trial results:

Cardiovascular outcomes study to evaluate the potential of aleglitazar to reduce cardiovascular risk in patients with a recent acute coronary syndrome (ACS) event and type 2 diabetes mellitus (T2D)

Summary

| | |
|--------------------------|-------------------------------|
| EudraCT number | 2009-012269-71 |
| Trial protocol | DE ES SE DK FR IE HU CZ GB IT |
| Global end of trial date | 18 November 2013 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 28 October 2016 |
| First version publication date | 28 October 2016 |

Trial information

Trial identification

| | |
|-----------------------|---------|
| Sponsor protocol code | BC22140 |
|-----------------------|---------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01042769 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | F. Hoffmann-La Roche AG |
| Sponsor organisation address | Grenzacherstrasse 124, Basel, Switzerland, CH-4070 |
| Public contact | global.trial_information@roche.com, F. Hoffmann-La Roche AG,, +41 61 687 83333, global.trial_information@roche.com |
| Scientific contact | +41 61 6878333,, Roche Trial Information Hotline,, +41 61 687 83333, global.trial_information@roche.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 | 17 December 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 18 November 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 18 November 2013 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

To determine whether aleglitazar reduces cardiovascular mortality and morbidity (defined as non-fatal myocardial infarction (MI) and non-fatal stroke) in patients with a recent ACS event and T2D.

Protection of trial subjects:

All participants signed an informed consent form before enrollment into the study.

Background therapy:

Contemporary evidence-based medical care for ACS (e.g., antiplatelets, beta-blockers, ACE-inhibitors, and statins), and diabetes (e.g., diet, exercise, antihyperglycemic medications).

Evidence for comparator: -

| | |
|---|-------------|
| Actual start date of recruitment | 03 May 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 | China: 631 |
| Country: Number of subjects enrolled | India: 602 |
| Country: Number of subjects enrolled | Korea, Republic of: 233 |
| Country: Number of subjects enrolled | Thailand: 232 |
| Country: Number of subjects enrolled | Malaysia: 120 |
| Country: Number of subjects enrolled | Australia: 98 |
| Country: Number of subjects enrolled | New Zealand: 61 |
| Country: Number of subjects enrolled | Russian Federation: 42 |
| Country: Number of subjects enrolled | Poland: 638 |
| Country: Number of subjects enrolled | Spain: 448 |
| Country: Number of subjects enrolled | Germany: 279 |
| Country: Number of subjects enrolled | Hungary: 251 |
| Country: Number of subjects enrolled | Italy: 157 |
| Country: Number of subjects enrolled | United Kingdom: 134 |
| Country: Number of subjects enrolled | Sweden: 132 |
| Country: Number of subjects enrolled | Czech Republic: 124 |
| Country: Number of subjects enrolled | Netherlands: 94 |
| Country: Number of subjects enrolled | France: 92 |
| Country: Number of subjects enrolled | Romania: 90 |
| Country: Number of subjects enrolled | Ireland: 43 |

| | |
|--------------------------------------|---------------------|
| Country: Number of subjects enrolled | Denmark: 28 |
| Country: Number of subjects enrolled | United States: 1094 |
| Country: Number of subjects enrolled | Canada: 545 |
| Country: Number of subjects enrolled | Mexico: 369 |
| Country: Number of subjects enrolled | Brazil: 533 |
| Country: Number of subjects enrolled | Argentina: 156 |
| Worldwide total number of subjects | 7226 |
| EEA total number of subjects | 2510 |

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) | 4836 |
| From 65 to 84 years | 2354 |
| 85 years and over | 36 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

An Eligibility Screening Form [ESF] documenting the investigator's assessment of each screened patient with regard to the protocol's inclusion and exclusion criteria was completed by the investigator.

Period 1

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

Arms

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

Arm description:

Aleglitazar 150 µg tablet

| | |
|--|----------------|
| Arm type | Experimental |
| Investigational medicinal product name | Aleglitazar |
| Investigational medicinal product code | Ro 72-8804/F23 |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Once daily

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

Arm description:

Placebo

| | |
|--|-------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Matching placebo tablet |
| Investigational medicinal product code | (Ro 72-8804/F20) |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Once daily

| Number of subjects in period 1 | Aleglitazar | Placebo |
|--------------------------------|-------------|---------|
| Started | 3616 | 3610 |
| Completed | 3244 | 3243 |
| Not completed | 372 | 367 |
| Adverse event, serious fatal | 147 | 139 |

| | | |
|------------------------------|-----|-----|
| Consent withdrawn by subject | 120 | 108 |
| Missing information | - | 1 |
| Lost to follow-up | 105 | 119 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Aleglitazar |
|-----------------------|-------------|

Reporting group description:

Aleglitazar 150 µg tablet

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

Reporting group description:

Placebo

| Reporting group values | Aleglitazar | Placebo | Total |
|------------------------|-------------|---------|-------|
| Number of subjects | 3616 | 3610 | 7226 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 2374 | 2462 | 4836 |
| From 65-84 years | 1220 | 1134 | 2354 |
| 85 years and over | 21 | 14 | 35 |
| Not recorded | 1 | 0 | 1 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 974 | 991 | 1965 |
| Male | 2641 | 2619 | 5260 |
| Not recorded | 1 | 0 | 1 |

End points

End points reporting groups

| | |
|------------------------------|-------------|
| Reporting group title | Aleglitazar |
| Reporting group description: | |
| Aleglitazar 150 µg tablet | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo | |

Primary: Number of patients with first occurrence of any component of a composite of cardiovascular death, nonfatal myocardial infarction and non-fatal stroke as adjudicated by the Clinical Events Committee (CEC)

| | |
|------------------------|---|
| End point title | Number of patients with first occurrence of any component of a composite of cardiovascular death, nonfatal myocardial infarction and non-fatal stroke as adjudicated by the Clinical Events Committee (CEC) |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3616 | 3610 | | |
| Units: Patients | 344 | 362 | | |

Statistical analyses

| | |
|---|-------------------------|
| Statistical analysis title | Primary outcome measure |
| Comparison groups | Placebo v Aleglitazar |
| Number of subjects included in analysis | 7226 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | = 0.566 |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.96 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.11 |

Secondary: Number of patients with other cardiovascular outcomes

| | |
|-----------------|---|
| End point title | Number of patients with other cardiovascular outcomes |
|-----------------|---|

End point description:

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

End point timeframe:

3 years

| End point values | Aleglitazar | Placebo | | |
|-------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3616 | 3610 | | |
| Units: Patients | | | | |
| Any cardiovascular death | 112 | 98 | | |
| Any non-fatal myocardial infarction | 212 | 239 | | |
| Any non-fatal stroke | 49 | 52 | | |
| All-cause mortality | 148 | 139 | | |
| Hosp. for unstable angina | 118 | 156 | | |
| Hosp. for heart failure | 122 | 100 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean absolute change from baseline to end of treatment in glycated hemoglobin (HbA1c)

| | |
|-----------------|---|
| End point title | Mean absolute change from baseline to end of treatment in glycated hemoglobin (HbA1c) |
|-----------------|---|

End point description:

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

End point timeframe:

3 years

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3362 | 3371 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | -0.7 (± 1.5) | -0.1 (± 1.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in low-density lipoprotein cholesterol (LDL-C)

| | |
|-----------------|---|
| End point title | Mean percentage change from baseline to end of treatment in low-density lipoprotein cholesterol (LDL-C) |
|-----------------|---|

End point description:

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

End point timeframe:

3 years

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3243 | 3212 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | 23.1 (± 50.8) | 16.6 (± 49) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in high-density lipoprotein cholesterol (HDL-C)

| | |
|-----------------|--|
| End point title | Mean percentage change from baseline to end of treatment in high-density lipoprotein cholesterol (HDL-C) |
|-----------------|--|

End point description:

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

End point timeframe:

3 years

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3301 | 3289 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | 24.8 (± 27.4) | 10.3 (± 23.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in triglycerides (TG)

| | |
|------------------------|--|
| End point title | Mean percentage change from baseline to end of treatment in triglycerides (TG) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3302 | 3290 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | -13.1 (± 46.5) | 22 (± 67.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in apolipoprotein A-I (ApoA1)

| | |
|------------------------|--|
| End point title | Mean percentage change from baseline to end of treatment in apolipoprotein A-I (ApoA1) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|--------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3296 | 3279 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | 10.3 (\pm 20.3) | 7.9 (\pm 18.3) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in apolipoprotein B (ApoB)

| | |
|------------------------|---|
| End point title | Mean percentage change from baseline to end of treatment in apolipoprotein B (ApoB) |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|-------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3296 | 3279 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | 4.8 (\pm 33.2) | 10.2 (\pm 32.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean absolute change from baseline to end of treatment in fibrinogen-C

| | |
|------------------------|--|
| End point title | Mean absolute change from baseline to end of treatment in fibrinogen-C |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|-----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3151 | 3145 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | -110.1 (\pm 139.5) | -68.2 (\pm 145.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Median percent change from baseline to end of treatment (Q1 – Q3) in high-sensitivity C-reactive protein (hs-CRP-C)

| | |
|-----------------|---|
| End point title | Median percent change from baseline to end of treatment (Q1 – Q3) in high-sensitivity C-reactive protein (hs-CRP-C) |
|-----------------|---|

End point description:

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

End point timeframe:
3 years

| End point values | Aleglitazar | Placebo | | |
|---------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3287 | 3291 | | |
| Units: Value | | | | |
| median (inter-quartile range (Q1-Q3)) | -31.5 (-70.7 to 35) | -23 (-64.9 to 43.7) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in adiponectin

| | |
|-----------------|---|
| End point title | Mean percentage change from baseline to end of treatment in adiponectin |
|-----------------|---|

End point description:

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

End point timeframe:
3 years

| End point values | Aleglitazar | Placebo | | |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3259 | 3235 | | |
| Units: Value | | | | |
| arithmetic mean (standard deviation) | 212 (\pm 214.2) | 16.2 (\pm 57.4) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patients with at least one adverse event

| | |
|------------------------|--|
| End point title | Number of patients with at least one adverse event |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3587 | 3587 | | |
| Units: Patients | 2719 | 2515 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Total number of adverse events

| | |
|------------------------|--------------------------------|
| End point title | Total number of adverse events |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3587 | 3587 | | |
| Units: AEs | 11853 | 10252 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Deaths

| | |
|------------------------|-----------|
| End point title | Deaths |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3587 | 3587 | | |
| Units: Deaths | 148 | 139 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with at least one serious adverse event

| | |
|------------------------|--|
| End point title | Patients with at least one serious adverse event |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| 3 years | |

| End point values | Aleglitazar | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3587 | 3587 | | |
| Units: Patients | 901 | 833 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with adverse events leading to withdrawal from treatment

| | |
|-----------------|---|
| End point title | Patients with adverse events leading to withdrawal from treatment |
|-----------------|---|

End point description:

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

End point timeframe:

3 years

| End point values | Aleglitazar | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3587 | 3587 | | |
| Units: Patients | 286 | 165 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 89 weeks.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 16.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Aleglitazar |
|-----------------------|-------------|

Reporting group description:

Aleglitazar 150 µg tablet

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

Reporting group description:

Placebo

| Serious adverse events | Aleglitazar | Placebo | |
|---|-------------------------|------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1015 / 3587 (28.30%) | 947 / 3587 (26.40%) | |
| number of deaths (all causes) | 2 | 2 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| PROSTATE CANCER | | | |
| subjects affected / exposed | 11 / 3587 (0.31%) | 13 / 3587 (0.36%) | |
| occurrences causally related to treatment / all | 1 / 11 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COLON CANCER | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 5 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ADENOCARCINOMA OF COLON | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| BLADDER CANCER | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3587 (0.11%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 2 / 4 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BREAST CANCER | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUNG ADENOCARCINOMA | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUNG NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| BASAL CELL CARCINOMA | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLADDER TRANSITIONAL CELL CARCINOMA | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PANCREATIC CARCINOMA METASTATIC | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| ADENOCARCINOMA GASTRIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTRIC CANCER | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| METASTASES TO LIVER | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RECTAL CANCER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RENAL CANCER | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RENAL CELL CARCINOMA | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SQUAMOUS CELL CARCINOMA OF LUNG | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| B-CELL LYMPHOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BILIARY CANCER METASTATIC | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| BREAST CANCER METASTATIC | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NON-SMALL CELL LUNG CANCER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| PANCREATIC CARCINOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| UTERINE LEIOMYOMA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACUTE LEUKAEMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACUTE MYELOID LEUKAEMIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ADENOCARCINOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ADENOCARCINOMA PANCREAS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ADENOID CYSTIC CARCINOMA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 EPIDIDYMIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BENIGN RENAL NEOPLASM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLADDER CANCER RECURRENT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLADDER NEOPLASM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BOWEN'S DISEASE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BREAST NEOPLASM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| BRONCHIAL CARCINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| CARCINOID TUMOUR OF THE DUODENUM | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CERVIX CARCINOMA STAGE II | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CLEAR CELL RENAL CELL CARCINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHRONIC MYELOMONOCYTIC LEUKAEMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COLON CANCER METASTATIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EAR NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EXTRANODAL MARGINAL ZONE B-CELL LYMPHOMA (MALT TYPE) | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENDOMETRIAL CANCER STAGE II | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| GASTROINTESTINAL CARCINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| GASTROINTESTINAL NEOPLASM | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| HEPATIC CANCER METASTATIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROINTESTINAL TRACT ADENOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HUERTHLE CELL CARCINOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTESTINAL ADENOCARCINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LARYNGEAL SQUAMOUS CELL CARCINOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INVASIVE LOBULAR BREAST CARCINOMA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LENTIGO MALIGNA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LIPOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUNG ADENOCARCINOMA METASTATIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUNG CANCER METASTATIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MALIGNANT MELANOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MALIGNANT NEOPLASM OF CONJUNCTIVA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MANTLE CELL LYMPHOMA STAGE IV | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MEDIASTINUM NEOPLASM | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| MENINGIOMA BENIGN | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| METASTASES TO ADRENALS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| METASTASES TO BONE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| METASTASES TO RETROPERITONEUM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| METASTATIC BRONCHIAL CARCINOMA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| METASTATIC MALIGNANT MELANOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MYELODYSPLASTIC SYNDROME | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| METASTATIC RENAL CELL CARCINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NON-HODGKIN'S LYMPHOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NEUROMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NON-SMALL CELL LUNG CANCER STAGE I | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NON-SMALL CELL LUNG CANCER STAGE IIIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
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| OESOPHAGEAL ADENOCARCINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| OESOPHAGEAL CARCINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PROSTATE CANCER METASTATIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RECTAL ADENOCARCINOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RENAL NEOPLASM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SALIVARY GLAND CANCER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SMALL CELL LUNG CANCER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| T-CELL LYMPHOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| THYROID ADENOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URETHRAL CANCER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| UTERINE CANCER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| HYPERTENSION | | | |
| subjects affected / exposed | 10 / 3587 (0.28%) | 12 / 3587 (0.33%) | |
| occurrences causally related to treatment / all | 1 / 10 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERTENSIVE CRISIS | | | |
| subjects affected / exposed | 8 / 3587 (0.22%) | 10 / 3587 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOTENSION | | | |
| subjects affected / exposed | 9 / 3587 (0.25%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERIPHERAL ISCHAEMIA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3587 (0.11%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| INTERMITTENT CLAUDICATION | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERIPHERAL ARTERIAL OCCLUSIVE DISEASE | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| AORTIC ANEURYSM | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACCELERATED HYPERTENSION | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DEEP VEIN THROMBOSIS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EXTREMITY NECROSIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTERIOSCLEROSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| DIABETIC VASCULAR DISORDER | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMATOMA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOVOLAEMIC SHOCK | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| PERIPHERAL VASCULAR DISORDER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERTENSIVE EMERGENCY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ILIAC ARTERY OCCLUSION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MALIGNANT HYPERTENSION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| THROMBOPHLEBITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTERIAL INSUFFICIENCY | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTERIAL SPASM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CIRCULATORY COLLAPSE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| DIABETIC MICROANGIOPATHY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FEMORAL ARTERY ANEURYSM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FEMORAL ARTERY EMBOLISM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FLUSHING | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ISCHAEMIC LIMB PAIN | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| JUGULAR VEIN THROMBOSIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LERICHE SYNDROME | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LYMPHOEDEMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NECROSIS ISCHAEMIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ORTHOSTATIC HYPOTENSION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERIPHERAL ARTERY ANEURYSM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERIPHERAL ARTERY THROMBOSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SHOCK HAEMORRHAGIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VARICOSE VEIN | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VASCULAR OCCLUSION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VASCULITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| KNEE ARTHROPLASTY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| AORTIC VALVE REPLACEMENT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CATARACT OPERATION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC PACEMAKER REPLACEMENT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FOOT AMPUTATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ILEOSTOMY | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IMPLANTABLE DEFIBRILLATOR INSERTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IMPLANTABLE DEFIBRILLATOR REMOVAL | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LEG AMPUTATION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PROSTATECTOMY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SCAR EXCISION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| THERAPY CHANGE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TOE AMPUTATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TRANSURETHRAL PROSTATECTOMY | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | | | |
| NON-CARDIAC CHEST PAIN | | | |
| subjects affected / exposed | 93 / 3587 (2.59%) | 73 / 3587 (2.04%) | |
| occurrences causally related to treatment / all | 2 / 118 | 4 / 81 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DEATH | | | |
| subjects affected / exposed | 9 / 3587 (0.25%) | 14 / 3587 (0.39%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 14 | |
| deaths causally related to treatment / all | 0 / 9 | 1 / 14 | |
| SUDDEN DEATH | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 10 / 3587 (0.28%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 1 / 6 | 0 / 10 | |
| SUDDEN CARDIAC DEATH | | | |
| subjects affected / exposed | 9 / 3587 (0.25%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 9 | 0 / 3 | |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 2 / 6 | 2 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHEST DISCOMFORT | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PYREXIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHEST PAIN | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FATIGUE | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IMPAIRED HEALING | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ASTHENIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC DEATH | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| LOCAL SWELLING | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MALAISE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHILLS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DEVICE BREAKAGE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DEVICE DISLOCATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DRUG INTOLERANCE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ELECTROCUTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| GAIT DISTURBANCE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GENERAL PHYSICAL HEALTH DETERIORATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HERNIA OBSTRUCTIVE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IMPLANT SITE HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MEDICAL DEVICE COMPLICATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MEDICAL DEVICE PAIN | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MULTI-ORGAN FAILURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NECROBIOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SURGICAL FAILURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| ALLERGY TO ARTHROPOD STING | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CONTRAST MEDIA ALLERGY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DRUG HYPERSENSITIVITY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FOOD ALLERGY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TRANSPLANT REJECTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| PHYSICAL ASSAULT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | | | |
| BENIGN PROSTATIC HYPERPLASIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| PROSTATITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ERECTILE DYSFUNCTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| OVARIAN CYST | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACQUIRED HYDROCELE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BREAST DYSPLASIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BREAST HAEMATOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENDOMETRIAL HYPERPLASIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EPIDIDYMITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GENITAL TRACT INFLAMMATION | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MENORRHAGIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PROSTATIC OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VAGINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VULVAL ULCERATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| DYSпноEA | | | |
| subjects affected / exposed | 22 / 3587 (0.61%) | 14 / 3587 (0.39%) | |
| occurrences causally related to treatment / all | 2 / 22 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 17 / 3587 (0.47%) | 15 / 3587 (0.42%) | |
| occurrences causally related to treatment / all | 0 / 25 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| PULMONARY OEDEMA | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 9 / 3587 (0.25%) | 12 / 3587 (0.33%) | |
| occurrences causally related to treatment / all | 1 / 9 | 2 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 8 / 3587 (0.22%) | 9 / 3587 (0.25%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PULMONARY EMBOLISM | | | |
| subjects affected / exposed | 10 / 3587 (0.28%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| RESPIRATORY FAILURE | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 7 / 3587 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 3 | |
| ACUTE PULMONARY OEDEMA | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 7 | 2 / 8 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DYSPNOEA EXERTIONAL | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 4 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACUTE RESPIRATORY FAILURE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ASTHMA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COUGH | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PLEURISY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PNEUMONIA ASPIRATION | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| PNEUMONITIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PULMONARY HYPERTENSION | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| SLEEP APNOEA SYNDROME | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BRONCHITIS CHRONIC | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EPISTAXIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOXIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PLEURITIC PAIN | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PULMONARY FIBROSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| RESPIRATORY DISTRESS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| ALLERGIC BRONCHITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHRONIC RESPIRATORY FAILURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DYSPHONIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMOPTYSIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMOTHORAX | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HICCUPS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYDROPNEUMOTHORAX | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTERSTITIAL LUNG DISEASE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NASAL POLYPS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ORTHOPNOEA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PNEUMOMEDIASTINUM | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PULMONARY THROMBOSIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RESPIRATORY ARREST | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Psychiatric disorders | | | |
| DEPRESSION | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ALCOHOL WITHDRAWAL SYNDROME | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DELIRIUM | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SUICIDE ATTEMPT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ALCOHOL ABUSE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ANXIETY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BREATHING-RELATED SLEEP DISORDER | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COMPLETED SUICIDE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| DELIRIUM TREMENS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DRUG DEPENDENCE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HOMICIDAL IDEATION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MENTAL STATUS CHANGES | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PANIC ATTACK | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PSYCHOTIC DISORDER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SOMATISATION DISORDER | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STRESS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SUICIDAL IDEATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| CHOLECYSTITIS ACUTE | | | |
| subjects affected / exposed | 9 / 3587 (0.25%) | 6 / 3587 (0.17%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHOLECYSTITIS | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 7 / 3587 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BILE DUCT STONE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHOLANGITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BILIARY COLIC | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BILE DUCT OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHOLANGITIS ACUTE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHOLECYSTITIS CHRONIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CIRRHOSIS ALCOHOLIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMOBILIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEPATIC CIRRHOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEPATIC FAILURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEPATITIS | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEPATITIS ACUTE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYDROCHOLECYSTIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| JAUNDICE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LIVER DISORDER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 10 / 3587 (0.28%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 7 / 10 | 2 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTERNATIONAL NORMALISED RATIO INCREASED | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLOOD CREATINE PHOSPHOKINASE INCREASED | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 2 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLOOD PRESSURE INCREASED | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TROPONIN INCREASED | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLOOD GLUCOSE INCREASED | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TRANSAMINASES INCREASED | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TROPONIN I INCREASED | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLOOD BILIRUBIN INCREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLOOD POTASSIUM DECREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLOOD PRESSURE DECREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BODY TEMPERATURE INCREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BLOOD URINE PRESENT | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC ENZYMES INCREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ELECTROCARDIOGRAM T WAVE INVERSION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EXERCISE TEST ABNORMAL | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GAMMA-GLUTAMYLTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GENERAL PHYSICAL CONDITION ABNORMAL | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GLOMERULAR FILTRATION RATE DECREASED | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMATOCRIT DECREASED | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMOGLOBIN DECREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEPATIC ENZYME INCREASED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Injury, poisoning and procedural complications | | | |
| FEMUR FRACTURE | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FALL | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HIP FRACTURE | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ANKLE FRACTURE | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HUMERUS FRACTURE | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SUBDURAL HAEMATOMA | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FOOT FRACTURE | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POST PROCEDURAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| LACERATION | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VASCULAR PSEUDOANEURYSM | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CONCUSSION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CORONARY ARTERY RESTENOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INCISIONAL HERNIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MENISCUS INJURY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POST PROCEDURAL HAEMATOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPINAL COMPRESSION FRACTURE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| THORACIC VERTEBRAL FRACTURE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TOXICITY TO VARIOUS AGENTS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHEST INJURY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CRANIOCEREBRAL INJURY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COMMINUTED FRACTURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FACIAL BONES FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FEMORAL NECK FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| JOINT INJURY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LIMB INJURY | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LOWER LIMB FRACTURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PATELLA FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PUBIS FRACTURE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ROAD TRAFFIC ACCIDENT | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| RADIUS FRACTURE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SUBDURAL HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| TENDON RUPTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| THERMAL BURN | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TIBIA FRACTURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACCIDENT | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACCIDENTAL OVERDOSE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACETABULUM FRACTURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ALCOHOL POISONING | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| AVULSION FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BONE FISSURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FIBULA FRACTURE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROINTESTINAL INJURY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IMPACTED FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEAD INJURY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| JOINT DISLOCATION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LIGAMENT SPRAIN | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LIMB TRAUMATIC AMPUTATION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUMBAR VERTEBRAL FRACTURE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MECHANICAL VENTILATION COMPLICATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MULTIPLE INJURIES | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| OVERDOSE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PELVIC FRACTURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POST PROCEDURAL SWELLING | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POSTOPERATIVE RESPIRATORY FAILURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POSTPERICARDIOTOMY SYNDROME | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PULMONARY CONTUSION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RESPIRATORY FUME INHALATION DISORDER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RIB FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPINAL FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STERNAL FRACTURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| UPPER LIMB FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VACCINATION COMPLICATION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VASCULAR GRAFT OCCLUSION | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VASCULAR GRAFT THROMBOSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VITH NERVE INJURY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| WOUND DEHISCENCE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| WOUND SECRETION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| WRIST FRACTURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| ATRIAL SEPTAL DEFECT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYDROCELE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERTROPHIC CARDIOMYOPATHY | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PHIMOSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PYLORIC STENOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SYRINGOMYELIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 | 86 / 3587 (2.40%) | 87 / 3587 (2.43%) | |
| occurrences causally related to treatment / all | 5 / 96 | 1 / 100 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 109 / 3587 (3.04%) | 62 / 3587 (1.73%) | |
| occurrences causally related to treatment / all | 21 / 147 | 12 / 93 | |
| deaths causally related to treatment / all | 1 / 11 | 0 / 8 | |
| CARDIAC FAILURE CONGESTIVE | | | |
| subjects affected / exposed | 63 / 3587 (1.76%) | 64 / 3587 (1.78%) | |
| occurrences causally related to treatment / all | 14 / 82 | 12 / 88 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 29 / 3587 (0.81%) | 20 / 3587 (0.56%) | |
| occurrences causally related to treatment / all | 1 / 40 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC ARREST | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 13 / 3587 (0.36%) | 13 / 3587 (0.36%) | |
| occurrences causally related to treatment / all | 0 / 13 | 1 / 13 | |
| deaths causally related to treatment / all | 0 / 11 | 1 / 10 | |
| CORONARY ARTERY DISEASE | | | |
| subjects affected / exposed | 11 / 3587 (0.31%) | 12 / 3587 (0.33%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 3 | |
| CARDIAC FAILURE ACUTE | | | |
| subjects affected / exposed | 11 / 3587 (0.31%) | 11 / 3587 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 14 | 1 / 12 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| ARRHYTHMIA | | | |
| subjects affected / exposed | 8 / 3587 (0.22%) | 9 / 3587 (0.25%) | |
| occurrences causally related to treatment / all | 1 / 8 | 1 / 9 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| VENTRICULAR TACHYCARDIA | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 6 | 2 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| MYOCARDIAL ISCHAEMIA | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| ACUTE LEFT VENTRICULAR FAILURE | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 5 / 5 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIOGENIC SHOCK | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 2 | |
| deaths causally related to treatment / all | 5 / 5 | 1 / 1 | |
| LEFT VENTRICULAR FAILURE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 7 / 3587 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | |
| AORTIC VALVE STENOSIS | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ATRIAL FLUTTER | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LEFT VENTRICULAR DYSFUNCTION | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 6 / 3587 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VENTRICULAR FIBRILLATION | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| BRADYCARDIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIO-RESPIRATORY ARREST | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| ISCHAEMIC CARDIOMYOPATHY | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| SICK SINUS SYNDROME | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ATRIOVENTRICULAR BLOCK COMPLETE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| CARDIAC DISCOMFORT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC FAILURE CHRONIC | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PALPITATIONS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CORONARY ARTERY STENOSIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERICARDITIS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ATRIOVENTRICULAR BLOCK | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERICARDIAL EFFUSION | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SUPRAVENTRICULAR TACHYCARDIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VENTRICULAR EXTRASYSTOLES | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ATRIAL TACHYCARDIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ATRIOVENTRICULAR BLOCK SECOND DEGREE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC ASTHMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EXTRASYSTOLES | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MITRAL VALVE INCOMPETENCE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RIGHT VENTRICULAR FAILURE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTERIOSPASM CORONARY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIAC AMYLOIDOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| CARDIAC TAMPONADE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIOMYOPATHY ACUTE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARDIOPULMONARY FAILURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| CARDIOVASCULAR DISORDER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| CARDIOVASCULAR INSUFFICIENCY | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHRONIC LEFT VENTRICULAR FAILURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHRONOTROPIC INCOMPETENCE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CORONARY ARTERY THROMBOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DRESSLER'S SYNDROME | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTRACARDIAC THROMBUS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LOW CARDIAC OUTPUT SYNDROME | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| PRINZMETAL ANGINA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RESTRICTIVE CARDIOMYOPATHY | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SINUS ARRHYTHMIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SINUS TACHYCARDIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STRESS CARDIOMYOPATHY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VENTRICULAR ARRHYTHMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VENTRICULAR FAILURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| SYNCOPE | | | |
| subjects affected / exposed | 22 / 3587 (0.61%) | 23 / 3587 (0.64%) | |
| occurrences causally related to treatment / all | 0 / 23 | 1 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TRANSIENT ISCHAEMIC ATTACK | | | |
| subjects affected / exposed | 10 / 3587 (0.28%) | 9 / 3587 (0.25%) | |
| occurrences causally related to treatment / all | 2 / 10 | 2 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CAROTID ARTERY STENOSIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3587 (0.11%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIZZINESS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEADACHE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETIC NEUROPATHY | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PRESYNCOPE | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VERTEBROBASILAR INSUFFICIENCY | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CARPAL TUNNEL SYNDROME | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CONVULSION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EPILEPSY | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3587 (0.08%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERTENSIVE ENCEPHALOPATHY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PARAESTHESIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VIITH NERVE PARALYSIS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CAROTID ARTERIOSCLEROSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DEMENTIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEMIPARESIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MIGRAINE | | | |

| | | |
|---|------------------|------------------|
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| SCIATICA | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| SUBARACHNOID HAEMORRHAGE | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 |
| ALCOHOLIC SEIZURE | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| ATAXIA | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| CAROTID ARTERY ANEURYSM | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| CAROTID ARTERY DISEASE | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| CEREBRAL ISCHAEMIA | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CEREBROVASCULAR INSUFFICIENCY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CERVICAL RADICULOPATHY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CERVICOBACHIAL SYNDROME | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COGNITIVE DISORDER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENCEPHALITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENCEPHALOPATHY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HEMIPLEGIC MIGRAINE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GRAND MAL CONVULSION | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOGLYCAEMIC COMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOGLYCAEMIC SEIZURE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOGLYCAEMIC UNCONSCIOUSNESS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPONATRAEMIC ENCEPHALOPATHY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUMBAR RADICULOPATHY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MEMORY IMPAIRMENT | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MENINGITIS NONINFECTIVE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| METABOLIC ENCEPHALOPATHY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MONOPARESIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NERVE COMPRESSION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NEURALGIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NORMAL PRESSURE HYDROCEPHALUS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPEECH DISORDER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | 1 / 3587 (0.03%) | 0 / 3587 (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 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VOCAL CORD PARALYSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 21 / 3587 (0.59%) | 18 / 3587 (0.50%) | |
| occurrences causally related to treatment / all | 0 / 27 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IRON DEFICIENCY ANAEMIA | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MICROCYTIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COAGULOPATHY | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERNICIOUS ANAEMIA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMORRHAGIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NORMOCHROMIC NORMOCYTIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PANCYTOPENIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPLENIC INFARCTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| VERTIGO | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VERTIGO POSITIONAL | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MIXED DEAFNESS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VESTIBULAR DISORDER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| CATARACT | | | |
| subjects affected / exposed | 9 / 3587 (0.25%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RETINAL ARTERY OCCLUSION | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VITREOUS HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| AMAUROSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CONJUNCTIVAL HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETIC RETINOPATHY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GLAUCOMA | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LENTICULAR OPACITIES | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VISUAL ACUITY REDUCED | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VISUAL IMPAIRMENT | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| UPPER GASTROINTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 22 / 3587 (0.61%) | 13 / 3587 (0.36%) | |
| occurrences causally related to treatment / all | 3 / 23 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTRIC ULCER HAEMORRHAGE | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LOWER GASTROINTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 10 / 3587 (0.28%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DUODENAL ULCER HAEMORRHAGE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 6 / 3587 (0.17%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PANCREATITIS ACUTE | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 6 / 3587 (0.17%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| GASTROESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INGUINAL HERNIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 6 / 3587 (0.17%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTRITIS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DYSPEPSIA | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROINTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LARGE INTESTINE POLYP | | | |

| | | |
|---|------------------|------------------|
| subjects affected / exposed | 5 / 3587 (0.14%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| PANCREATITIS | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 4 / 3587 (0.11%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| GASTRIC ULCER | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| HAEMORRHOIDS | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| MELAENA | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| RECTAL HAEMORRHAGE | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| VOMITING | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 5 / 3587 (0.14%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 |
| CONSTIPATION | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 3 / 3587 (0.08%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| DIARRHOEA | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIVERTICULUM | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DYSPHAGIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NAUSEA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTRITIS EROSIVE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HIATUS HERNIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SMALL INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL HERNIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ANAL HAEMORRHAGE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COLITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIVERTICULITIS INTESTINAL HAEMORRHAGIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIVERTICULUM INTESTINAL HAEMORRHAGIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENTERITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROINTESTINAL ANGIODYSPLASIA HAEMORRHAGIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IMPAIRED GASTRIC EMPTYING | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INGUINAL HERNIA, OBSTRUCTIVE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTESTINAL OBSTRUCTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTESTINAL PERFORATION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| PEPTIC ULCER HAEMORRHAGE | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL ADHESIONS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL PAIN LOWER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL WALL HAEMATOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHANGE OF BOWEL HABIT | | | |

| | | |
|---|------------------|------------------|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 / 3587 (0.03%) | 0 / 3587 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| COLITIS ULCERATIVE | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| DIVERTICULAR PERFORATION | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| DIVERTICULUM INTESTINAL | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| DUODENAL STENOSIS | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| DUODENITIS | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| EPIGASTRIC DISCOMFORT | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| FOOD POISONING | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTRIC ANTRAL VASCULAR ECTASIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTRODUODENAL ULCER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTRODUODENITIS HAEMORRHAGIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROINTESTINAL DISORDER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROINTESTINAL NECROSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| GASTROINTESTINAL ULCER HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GINGIVAL BLEEDING | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMATEMESIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMORRHAGIC EROSIVE GASTRITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ILEUS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INGUINAL HERNIA STRANGULATED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTESTINAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| LARGE INTESTINE PERFORATION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| OESOPHAGITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PANCREATITIS NECROTISING | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PEPTIC ULCER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERITONEAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PNEUMOPERITONEUM | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PROCTALGIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RETROPERITONEAL HAEMATOMA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SIGMOIDITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SMALL INTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SMALL INTESTINAL ULCER HAEMORRHAGE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SUBILEUS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| UMBILICAL HERNIA, OBSTRUCTIVE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 | | | |
| SKIN ULCER | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETIC FOOT | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| DECUBITUS ULCER | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PSORIASIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DERMATITIS ALLERGIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ECCHYMOSIS | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PEMPHIGUS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RASH GENERALISED | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SKIN FISSURES | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| RENAL FAILURE ACUTE | | | |
| subjects affected / exposed | 33 / 3587 (0.92%) | 22 / 3587 (0.61%) | |
| occurrences causally related to treatment / all | 12 / 35 | 4 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | |
| RENAL FAILURE | | | |
| subjects affected / exposed | 14 / 3587 (0.39%) | 12 / 3587 (0.33%) | |
| occurrences causally related to treatment / all | 0 / 14 | 2 / 12 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| RENAL IMPAIRMENT | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 6 / 3587 (0.17%) | |
| occurrences causally related to treatment / all | 3 / 6 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMATURIA | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 5 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NEPHROLITHIASIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 6 / 3587 (0.17%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RENAL FAILURE CHRONIC | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URINARY RETENTION | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RENAL COLIC | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CALCULUS URETERIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CALCULUS URINARY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYDRONEPHROSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PRERENAL FAILURE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RENAL ARTERY STENOSIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URETHRAL STENOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| AZOTAEMIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| BLADDER TAMPONADE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CYSTITIS HAEMORRHAGIC | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETIC NEPHROPATHY | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NEPHRITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RENAL CYST | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URINARY TRACT OBSTRUCTION | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URINOMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| HYPERTHYROIDISM | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| ADRENOCORTICAL INSUFFICIENCY ACUTE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| No Coding available | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| OSTEOARTHRITIS | | | |
| subjects affected / exposed | 14 / 3587 (0.39%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 6 / 3587 (0.17%) | 9 / 3587 (0.25%) | |
| occurrences causally related to treatment / all | 0 / 6 | 2 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BACK PAIN | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| INTERVERTEBRAL DISC PROTRUSION | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MUSCULOSKELETAL PAIN | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MYALGIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTHRITIS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RHEUMATOID ARTHRITIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPINAL OSTEOARTHRITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RHABDOMYOLYSIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUMBAR SPINAL STENOSIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPINAL COLUMN STENOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MUSCULAR WEAKNESS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TENDONITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTHRITIS REACTIVE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EXOSTOSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTERVERTEBRAL DISC DISORDER | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MUSCLE HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MYOPATHY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| OSTEOCHONDROSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PALINDROMIC RHEUMATISM | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ROTATOR CUFF SYNDROME | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SCLERODERMA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPINAL DISORDER | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPINAL PAIN | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SPONDYLITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SYSTEMIC LUPUS ERYTHEMATOSUS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (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 | | | |
| PNEUMONIA | | | |
| subjects affected / exposed | 43 / 3587 (1.20%) | 40 / 3587 (1.12%) | |
| occurrences causally related to treatment / all | 0 / 47 | 0 / 45 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 3 | |
| CELLULITIS | | | |
| subjects affected / exposed | 24 / 3587 (0.67%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 27 | 1 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 12 / 3587 (0.33%) | 20 / 3587 (0.56%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 22 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SEPSIS | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 10 / 3587 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| SEPTIC SHOCK | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3587 (0.11%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 5 | |
| BRONCHITIS | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 7 / 3587 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LOCALISED INFECTION | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 6 / 3587 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GANGRENE | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 6 / 3587 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BRONCHOPNEUMONIA | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| LOWER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 5 / 3587 (0.14%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| OSTEOMYELITIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| APPENDICITIS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POSTOPERATIVE WOUND INFECTION | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| WOUND INFECTION | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ERYSIPELAS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 5 / 3587 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUNG INFECTION | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DENGUE FEVER | | | |
| subjects affected / exposed | 4 / 3587 (0.11%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIVERTICULITIS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PYELONEPHRITIS ACUTE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SUBCUTANEOUS ABSCESS | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ARTHRITIS BACTERIAL | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROINTESTINAL INFECTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MEDIASTINITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ORCHITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PYELONEPHRITIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STAPHYLOCOCCAL SEPSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| UPPER RESPIRATORY TRACT INFECTION | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| UROSEPSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABSCESS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABSCESS LIMB | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABSCESS NECK | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACUTE TONSILLITIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ANAL ABSCESS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BACTERAEemia | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENDOCARDITIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| IMPLANT SITE INFECTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INFECTED SKIN ULCER | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INFLUENZA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERIRECTAL ABSCESS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERITONITIS | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| PHARYNGITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TRACHEOBRONCHITIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ABDOMINAL WALL INFECTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACQUIRED IMMUNODEFICIENCY SYNDROME | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ACTINOMYCOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ATYPICAL PNEUMONIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BACTERIAL SEPSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| BONE TUBERCULOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BREAST ABSCESS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BRONCHITIS BACTERIAL | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| BURSITIS INFECTIVE | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CANDIDA PNEUMONIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CANDIDA SEPSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CELLULITIS OF MALE EXTERNAL GENITAL ORGAN | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CELLULITIS STREPTOCOCCAL | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHEST WALL ABSCESS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CYSTITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| CHOLECYSTITIS INFECTIVE | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETIC FOOT INFECTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| EAR TUBERCULOSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENDOMETRITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENDOCARDITIS BACTERIAL | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ENDOPHTHALMITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ESCHERICHIA BACTERAEMIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ESCHERICHIA URINARY TRACT INFECTION | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROENTERITIS ROTAVIRUS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GASTROENTERITIS VIRAL | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GENITOURINARY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| GRAFT INFECTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HAEMATOMA INFECTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| 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 | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INCISION SITE CELLULITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HISTOPLASMOSIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| INTESTINAL GANGRENE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| KLEBSIELLA SEPSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LIVER ABSCESS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LOWER RESPIRATORY TRACT INFECTION VIRAL | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| LUDWIG ANGINA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| MASTOIDITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NASAL ABSCESS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| NECROTISING FASCIITIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| NEUROCYSTICERCOSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| OTITIS MEDIA CHRONIC | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PARONYCHIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERIODONTITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PERITONITIS BACTERIAL | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| PERITONSILLAR ABSCESS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PILONIDAL CYST | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PNEUMONIA KLEBSIELLA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POST PROCEDURAL CELLULITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POST PROCEDURAL INFECTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| POST PROCEDURAL PNEUMONIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PSEUDOMEMBRANOUS COLITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PULMONARY SEPSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| PULMONARY TUBERCULOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| PYONEPHROSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SALPINGITIS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SCROTAL ABSCESS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SKIN INFECTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SOFT TISSUE INFECTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STAPHYLOCOCCAL BACTERAEMIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STAPHYLOCOCCAL INFECTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STERNITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| STREPTOCOCCAL ABSCESS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TYPHOID FEVER | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URETERITIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| URINARY TRACT INFECTION PSEUDOMONAL | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VARICELLA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VIRAL INFECTION | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VIRAL SINUSITIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| WOUND INFECTION STAPHYLOCOCCAL | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| HYPOGLYCAEMIA | | | |
| subjects affected / exposed | 39 / 3587 (1.09%) | 17 / 3587 (0.47%) | |
| occurrences causally related to treatment / all | 20 / 42 | 6 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERGLYCAEMIA | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 8 / 3587 (0.22%) | 10 / 3587 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DEHYDRATION | | | |
| subjects affected / exposed | 7 / 3587 (0.20%) | 8 / 3587 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETES MELLITUS INADEQUATE CONTROL | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 9 / 3587 (0.25%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 4 / 3587 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETES MELLITUS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 3 / 3587 (0.08%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DIABETIC KETOACIDOSIS | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 3 / 3587 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPONATRAEMIA | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3587 (0.03%) | 2 / 3587 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FLUID OVERLOAD | | | |
| subjects affected / exposed | 2 / 3587 (0.06%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| FLUID RETENTION | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPERPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| KETOACIDOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| METABOLIC ACIDOSIS | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| TYPE 2 DIABETES MELLITUS | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3587 (0.00%) | 1 / 3587 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| OBESITY | | | |
| subjects affected / exposed | 1 / 3587 (0.03%) | 0 / 3587 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Aleglitazar | Placebo | |
|---|----------------------|----------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1514 / 3587 (42.21%) | 1119 / 3587 (31.20%) | |
| Investigations | | | |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 395 / 3587 (11.01%) | 171 / 3587 (4.77%) | |
| occurrences (all) | 417 | 180 | |
| BLOOD CREATININE INCREASED | | | |
| subjects affected / exposed | 231 / 3587 (6.44%) | 93 / 3587 (2.59%) | |
| occurrences (all) | 279 | 105 | |
| Vascular disorders | | | |
| HYPERTENSION | | | |
| subjects affected / exposed | 165 / 3587 (4.60%) | 183 / 3587 (5.10%) | |
| occurrences (all) | 182 | 197 | |
| Cardiac disorders | | | |
| ANGINA PECTORIS | | | |
| subjects affected / exposed | 220 / 3587 (6.13%) | 223 / 3587 (6.22%) | |
| occurrences (all) | 253 | 258 | |
| General disorders and administration site conditions | | | |
| NON-CARDIAC CHEST PAIN | | | |
| subjects affected / exposed | 198 / 3587 (5.52%) | 224 / 3587 (6.24%) | |
| occurrences (all) | 248 | 265 | |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 470 / 3587 (13.10%) | 225 / 3587 (6.27%) | |
| occurrences (all) | 544 | 266 | |

| | | | |
|------------------------------------|------------------------|------------------------|--|
| Metabolism and nutrition disorders | | | |
| HYPOGLYCAEMIA | | | |
| subjects affected / exposed | 579 / 3587 (16.14%) | 389 / 3587 (10.84%) | |
| occurrences (all) | 1555 | 1004 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|--|
| 25 February 2013 | Added a study drug discontinuation criterion for patients who experienced a serious GI hemorrhage. This was done to address advice received from the Data Safety Monitoring Board. 25-Feb-2013 |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported