



Clinical trial results:

An International, Double-blind, Randomised, Placebo-Controlled Phase IIIb Study to Evaluate the Effect of Dapagliflozin on Reducing CV Death or Worsening Heart Failure in Patients with Heart Failure with Preserved Ejection Fraction (HFpEF).

DELIVER - Dapagliflozin Evaluation to Improve the LIVEs of Patients with PReserved Ejection Fraction Heart Failure

Summary

| | |
|--------------------------|----------------------|
| EudraCT number | 2018-000802-46 |
| Trial protocol | CZ NL ES PL HU BE RO |
| Global end of trial date | 27 March 2022 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 01 April 2023 |
| First version publication date | 01 April 2023 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | D169CC00001 |
|-----------------------|-------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | AstraZeneca AB |
| Sponsor organisation address | Vastra Malarehamnen 9, Södertälje, Sweden, 151 85 |
| Public contact | Global Clinical Lead, AstraZeneca AB, +1 877-240-9479, Information.center@astrazeneca.com |
| Scientific contact | Global Clinical Lead, AstraZeneca AB, +1 877-240-9479, Information.center@astrazeneca.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 27 March 2022 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 27 March 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 27 March 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To determine whether dapagliflozin is superior to placebo, when added to standard of care, in reducing the composite of CV death and HF events (hospitalisation for HF or urgent HF visit) in patients with HF and preserved systolic function in

- full study population

- subpopulation with LVEF <60%

Protection of trial subjects:

N/A

Background therapy:

Patients included in DELIVER were treated according to local guideline recommended therapy for HF symptoms (eg, diuretics) and co-morbidities (including treatment for hypertension, ischaemic heart disease, and atrial fibrillation, diabetes, hyperlipidaemia).

Evidence for comparator:

Placebo was selected as the control treatment because at the time of study initiation there was no approved pharmacological intervention for HF and LVEF > 40% that could be used as a comparator.

| | |
|---|----------------|
| Actual start date of recruitment | 27 August 2018 |
| 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 | Argentina: 320 |
| Country: Number of subjects enrolled | Belgium: 64 |
| Country: Number of subjects enrolled | Brazil: 405 |
| Country: Number of subjects enrolled | Bulgaria: 493 |
| Country: Number of subjects enrolled | Canada: 299 |
| Country: Number of subjects enrolled | China: 310 |
| Country: Number of subjects enrolled | Czechia: 274 |
| Country: Number of subjects enrolled | Hungary: 466 |
| Country: Number of subjects enrolled | Japan: 422 |
| Country: Number of subjects enrolled | Mexico: 216 |

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Netherlands: 176 |
| Country: Number of subjects enrolled | Peru: 240 |
| Country: Number of subjects enrolled | Poland: 572 |
| Country: Number of subjects enrolled | Romania: 61 |
| Country: Number of subjects enrolled | Russian Federation: 401 |
| Country: Number of subjects enrolled | Saudi Arabia: 190 |
| Country: Number of subjects enrolled | Spain: 308 |
| Country: Number of subjects enrolled | Taiwan: 318 |
| Country: Number of subjects enrolled | United States: 552 |
| Country: Number of subjects enrolled | Viet Nam: 176 |
| Worldwide total number of subjects | 6263 |
| EEA total number of subjects | 2414 |

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) | 1345 |
| From 65 to 84 years | 4466 |
| 85 years and over | 452 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

At the first visit, i.e. the enrollment visit 1, patients were evaluated regarding the protocol mandated inclusion and exclusion criteria.

Period 1

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

Arms

| | |
|------------------------------|------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Dapa 10 mg |

Arm description:

Dapagliflozin 10 mg tablets administered once daily per oral use

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Dapagliflozin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Dapagliflozin 10 mg tablets administered orally once daily

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

Arm description:

Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use

| | |
|--|----------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Matching placebo for dapagliflozin 10 mg tablets administered orally once daily

| Number of subjects in period 1 | Dapa 10 mg | Placebo |
|---------------------------------------|------------|---------|
| Started | 3131 | 3132 |
| Completed | 3121 | 3121 |
| Not completed | 10 | 11 |
| Consent withdrawn by subject | 8 | 10 |

| | | |
|-------------------|---|---|
| Lost to follow-up | 2 | 1 |
|-------------------|---|---|

Baseline characteristics

Reporting groups

| | |
|--|------------|
| Reporting group title | Dapa 10 mg |
| Reporting group description: | |
| Dapagliflozin 10 mg tablets administered once daily per oral use | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use | |

| Reporting group values | Dapa 10 mg | Placebo | Total |
|---|------------|---------|-------|
| Number of subjects | 3131 | 3132 | 6263 |
| Age Categorical | | | |
| Units: Participants | | | |
| <= 50 | 85 | 74 | 159 |
| > 50 | 3046 | 3058 | 6104 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 71.8 | 71.5 | |
| standard deviation | ± 9.6 | ± 9.5 | - |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 1364 | 1383 | 2747 |
| Male | 1767 | 1749 | 3516 |
| Age, Customized | | | |
| Units: Subjects | | | |
| <= 65 | 743 | 761 | 1504 |
| >65 - 75 | 1184 | 1228 | 2412 |
| > 75 | 1204 | 1143 | 2347 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 632 | 598 | 1230 |
| Not Hispanic or Latino | 2499 | 2534 | 5033 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Race/Ethnicity, Customized | | | |
| Units: Subjects | | | |
| White | 2214 | 2225 | 4439 |
| Black or African American | 81 | 78 | 159 |
| Asian | 630 | 644 | 1274 |
| Native Hawaiian or other Pacific Islander | 0 | 0 | 0 |
| American Indian or Alaska Native | 93 | 96 | 189 |
| Other | 113 | 89 | 202 |
| Prior HF Hospitalization | | | |
| Units: Subjects | | | |
| Yes | 1270 | 1269 | 2539 |
| No | 1861 | 1863 | 3724 |
| NYHA Class at Baseline | | | |
| Units: Subjects | | | |

| | | | |
|---|-------|-------|------|
| NYHA class I | 0 | 1 | 1 |
| NYHA class II | 2314 | 2399 | 4713 |
| NYHA class III | 807 | 724 | 1531 |
| NYHA class IV | 10 | 8 | 18 |
| Medical History of Type 2 Diabetes Units: Subjects | | | |
| Yes | 1401 | 1405 | 2806 |
| No | 1730 | 1727 | 3457 |
| LVEF (%) at Baseline Units: Percentage of blood leaving the heart | | | |
| arithmetic mean | 54.0 | 54.3 | |
| standard deviation | ± 8.6 | ± 8.9 | - |

End points

End points reporting groups

| | |
|--|------------|
| Reporting group title | Dapa 10 mg |
| Reporting group description: Dapagliflozin 10 mg tablets administered once daily per oral use | |
| Reporting group title | Placebo |
| Reporting group description: Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use | |

Primary: Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure

| | |
|--|--|
| End point title | Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure |
| End point description: Dual primary efficacy | |
| Primary endpoint analysed in all patients randomised (Full analysis set) | |
| End point type | Primary |
| End point timeframe: Up to 42.1 months | |

| End point values | Dapa 10 mg | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3131 | 3132 | | |
| Units: Participants | | | | |
| Number of participants with an event | 512 | 610 | | |

Statistical analyses

| | |
|--|----------------------------|
| Statistical analysis title | Cox regression |
| Statistical analysis description: Comparison Group: Placebo | |
| Comparison groups | Dapa 10 mg v Placebo |
| Number of subjects included in analysis | 6263 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[1] |
| P-value | = 0.0008 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.82 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.73 |
| upper limit | 0.92 |

Notes:

[1] - Analysed in all randomized patients

Primary: Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure for LVEF <60% subpopulation

| | |
|--|--|
| End point title | Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure for LVEF <60% subpopulation |
| End point description: | |
| Dual primary efficacy | |
| Primary endpoint analysed in all patients randomised with LVEF < 60% at baseline | |
| End point type | Primary |
| End point timeframe: | |
| Up to 42.1 months | |

| | | | | |
|--------------------------------------|-----------------|-----------------|--|--|
| End point values | Dapa 10 mg | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2200 | 2172 | | |
| Units: Participants | | | | |
| Number of participants with an event | 381 | 440 | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Cox regression |
| Statistical analysis description: | |
| Comparison Group: Placebo | |
| Comparison groups | Dapa 10 mg v Placebo |
| Number of subjects included in analysis | 4372 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[2] |
| P-value | = 0.0085 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.83 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.73 |
| upper limit | 0.95 |

Notes:

[2] - Analysed in all randomized patients with LVEF < 60% at baseline

Secondary: Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit)

| | |
|-----------------|---|
| End point title | Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit) |
|-----------------|---|

End point description:

Secondary efficacy

Total number of heart failure events (first and recurrent) and cardiovascular death, analysed in all randomized patients

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

End point timeframe:

Up to 42.1 months

| | | | | |
|-----------------------------|-----------------|-----------------|--|--|
| End point values | Dapa 10 mg | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3131 | 3132 | | |
| Units: Number of events | 815 | 1057 | | |

Statistical analyses

| | |
|-----------------------------------|--------------------------|
| Statistical analysis title | Recurrent event analysis |
|-----------------------------------|--------------------------|

Statistical analysis description:

Comparison Group: Placebo

| | |
|-------------------|----------------------|
| Comparison groups | Dapa 10 mg v Placebo |
|-------------------|----------------------|

| | |
|---|------|
| Number of subjects included in analysis | 6263 |
|---|------|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|----------------------------|
| Analysis type | superiority ^[3] |
|---------------|----------------------------|

| | |
|---------|----------|
| P-value | = 0.0003 |
|---------|----------|

| | |
|--------|-------------------------------|
| Method | LWYY proportional rates model |
|--------|-------------------------------|

| | |
|--------------------|-----------------|
| Parameter estimate | Rate Ratio (RR) |
|--------------------|-----------------|

| | |
|----------------|------|
| Point estimate | 0.77 |
|----------------|------|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|------|
| lower limit | 0.67 |
|-------------|------|

| | |
|-------------|------|
| upper limit | 0.89 |
|-------------|------|

Notes:

[3] - Analysed in all randomized patients

Secondary: Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit) for LVEF <60% subpopulation

| | |
|--|---|
| End point title | Events included in the Composite Endpoint of CV Death or Recurrent Heart Failure Event (Hospitalization due to Heart Failure or Urgent Heart Failure Visit) for LVEF <60% subpopulation |
| End point description: Secondary efficacy | |
| Total number of heart failure events (first and recurrent) and cardiovascular death, analysed in all randomized patients with LVEF < 60% at baseline | |
| End point type | Secondary |
| End point timeframe: Up to 42.1 months | |

| | | | | |
|-----------------------------|-----------------|-----------------|--|--|
| End point values | Dapa 10 mg | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2200 | 2172 | | |
| Units: Number of events | 605 | 782 | | |

Statistical analyses

| | |
|--|-------------------------------|
| Statistical analysis title | Recurrent event analysis |
| Statistical analysis description: Comparison Group: Placebo | |
| Comparison groups | Dapa 10 mg v Placebo |
| Number of subjects included in analysis | 4372 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[4] |
| P-value | = 0.0017 |
| Method | LWYY proportional rates model |
| Parameter estimate | Rate Ratio (RR) |
| Point estimate | 0.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.65 |
| upper limit | 0.9 |

Notes:

[4] - Analysed in all randomized patients with LVEF < 60% at baseline

Secondary: Change From Baseline in the KCCQ Total Symptom Score at 8 Months

| | |
|---|--|
| End point title | Change From Baseline in the KCCQ Total Symptom Score at 8 Months |
| End point description: KCCQ is a 23-item, self-administered instrument that quantifies physical function, symptoms (frequency, severity and recent change), social function, self-efficacy and knowledge, and quality of life. The KCCQ Total Symptom Score incorporates the symptom domains into a single score. Scores are transformed to a range of 0-100, in which higher scores reflect better health status. | |
| End point type | Secondary |

End point timeframe:

Baseline and 8 months or death before 8 months

| | | | | |
|--------------------------------------|-------------------|-------------------|--|--|
| End point values | Dapa 10 mg | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1316 | 1311 | | |
| Units: Scores on a scale | | | | |
| arithmetic mean (standard deviation) | 8.3 (\pm 20.3) | 5.2 (\pm 21.1) | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Win ratio analysis |
| Statistical analysis description: | |
| Comparison Group: Placebo | |
| Comparison groups | Dapa 10 mg v Placebo |
| Number of subjects included in analysis | 2627 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[5] |
| P-value | = 0.0086 ^[6] |
| Method | Win Ratio |
| Parameter estimate | Rate Ratio (RR) |
| Point estimate | 1.11 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.03 |
| upper limit | 1.21 |

Notes:

[5] - Full analysis set population, including only assessments performed or planned prior to March 11th, 2020, when COVID-19 was declared a pandemic by the WHO.

[6] - The p-value is obtained from a rank ANCOVA adjusted for baseline KCCQ score, stratified by T2DM status at randomisation.

Secondary: Subjects Included in the Endpoint of Cardiovascular Death

| | |
|------------------------|---|
| End point title | Subjects Included in the Endpoint of Cardiovascular Death |
| End point description: | |
| Secondary efficacy | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 42.1 months | |

| End point values | Dapa 10 mg | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3131 | 3132 | | |
| Units: Participants | | | | |
| Number of participants with an event | 231 | 261 | | |

Statistical analyses

| Statistical analysis title | Cox regression |
|---|----------------------|
| Statistical analysis description: | |
| Comparison Group: Placebo | |
| Comparison groups | Dapa 10 mg v Placebo |
| Number of subjects included in analysis | 6263 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1678 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.74 |
| upper limit | 1.05 |

Secondary: Subjects Included in the Endpoint of All-cause Mortality

| | |
|------------------------|--|
| End point title | Subjects Included in the Endpoint of All-cause Mortality |
| End point description: | |
| Secondary efficacy | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 42.1 months | |

| End point values | Dapa 10 mg | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3131 | 3132 | | |
| Units: Participants | | | | |
| Number of participants with an event | 497 | 526 | | |

Statistical analyses

| | |
|---|----------------------|
| Statistical analysis title | Cox regression |
| Statistical analysis description: | |
| Comparison Group: Placebo | |
| Comparison groups | Dapa 10 mg v Placebo |
| Number of subjects included in analysis | 6263 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.3425 |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.07 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until last study visit

Adverse event reporting additional description:

Safety analysis set: randomized patients who received at least 1 dose of study drug

Systematic: Serious AEs, AEs leading to discontinuation / amputation or preceding events / potential endpoint / interruption of study drug, non-serious AEs: MI, unstable angina, stroke, major hypoglycaemic events, potential DKA and amputation.

Non-systematic: Other AEs

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 24.1 |

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | Dapa 10 mg |
|-----------------------|------------|

Reporting group description:

Dapagliflozin 10 mg tablets administered once daily per oral use

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

Reporting group description:

Placebo tablet to match dapagliflozin 10 mg, given once daily per oral use

| Serious adverse events | Dapa 10 mg | Placebo | |
|---|-------------------------|-------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1454 / 3126 (46.51%) | 1508 / 3127 (48.23%) | |
| number of deaths (all causes) | 509 | 532 | |
| number of deaths resulting from adverse events | 507 | 529 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adrenal gland cancer metastatic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma pancreas | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| B-cell lymphoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute leukaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma gastric | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Adenocarcinoma metastatic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Adenocarcinoma of colon | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | |
| Adrenal neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3126 (0.13%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Bile duct cancer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer recurrent | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma recurrent | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Breast cancer metastatic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Breast cancer recurrent | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial carcinoma | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Gastric neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 9 / 3127 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer recurrent | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Colon neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal adenocarcinoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ductal adenocarcinoma of pancreas | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Endometrial cancer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial cancer metastatic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Essential thrombocythaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fallopian tube cancer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Follicular lymphoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Colon adenoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3126 (0.13%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal lymphoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Intracranial meningioma malignant | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive breast carcinoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint neoplasm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Lung cancer metastatic | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 3 | |
| Gastrointestinal tract adenoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm prostate | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myeloproliferative neoplasm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Oesophageal neoplasm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lymphoplasmacytoid lymphoma/immunocytoma | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoproliferative disorder | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant neoplasm of unknown primary site | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Mediastinum neoplasm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastases to liver | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic carcinoma of the bladder | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic gastric cancer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Oropharyngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ovarian neoplasm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Pancreatic neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Parathyroid tumour benign | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma cell myeloma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasmacytoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural mesothelioma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Prostate cancer recurrent | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Rectal cancer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal neoplasm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Refractory cytopenia with unilineage dysplasia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cancer metastatic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal cancer metastatic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Tumour associated fever | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoma | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seborrhoeic keratosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Small cell lung cancer extensive stage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestine carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Squamous cell carcinoma of the vulva | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Thyroid cancer | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Triple negative breast cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tumour embolism | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Uterine neoplasm | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Waldenstrom's macroglobulinaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Tumour perforation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lung squamous cell carcinoma stage IV | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Adult T-cell lymphoma/leukaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diffuse large B-cell lymphoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Lung adenocarcinoma stage I | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 IV | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm rupture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Aortic dissection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stenosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3126 (0.13%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bleeding varicose vein | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral artery aneurysm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematocoele | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive urgency | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 3 / 10 | 0 / 6 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hypovolaemic shock | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Iliac artery stenosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoedema | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant hypertension | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 24 / 3126 (0.77%) | 18 / 3127 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 24 | 2 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 14 / 3126 (0.45%) | 9 / 3127 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral embolism | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicose ulceration | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicose vein | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular insufficiency | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis limb | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vessel perforation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral ischaemia | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 9 / 3127 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Death | | | |
| subjects affected / exposed | 54 / 3126 (1.73%) | 52 / 3127 (1.66%) | |
| occurrences causally related to treatment / all | 0 / 54 | 0 / 52 | |
| deaths causally related to treatment / all | 0 / 54 | 0 / 52 | |
| Asthenia | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cardiac death | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 3 | |
| Catheter site pain | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 7 / 3126 (0.22%) | 9 / 3127 (0.29%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural failure | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prosthetic cardiac valve thrombosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypothermia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired healing | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated hernia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site joint inflammation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multimorbidity | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Non-cardiac chest pain | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 7 / 3126 (0.22%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema due to cardiac disease | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden cardiac death | | | |
| subjects affected / exposed | 26 / 3126 (0.83%) | 37 / 3127 (1.18%) | |
| occurrences causally related to treatment / all | 1 / 26 | 1 / 37 | |
| deaths causally related to treatment / all | 1 / 26 | 1 / 37 | |
| Sudden death | | | |
| subjects affected / exposed | 24 / 3126 (0.77%) | 26 / 3127 (0.83%) | |
| occurrences causally related to treatment / all | 0 / 24 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 24 | 0 / 26 | |
| Ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent stenosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent thrombosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stent-graft endoleak | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Amyloidosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart transplant rejection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Primary amyloidosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Cardiac assistance device user | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Abnormal uterine bleeding | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acquired phimosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Breast mass | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial atrophy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heavy menstrual bleeding | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermenstrual bleeding | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal ulcer | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine prolapse | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulvovaginal inflammation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign prostatic hyperplasia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 3126 (0.13%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 16 / 3126 (0.51%) | 17 / 3127 (0.54%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 20 | |
| deaths causally related to treatment / all | 0 / 9 | 0 / 6 | |
| Acute pulmonary oedema | | | |
| subjects affected / exposed | 8 / 3126 (0.26%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Allergic respiratory symptom | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspiration | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 9 / 3127 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiectasis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Choking | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 21 / 3126 (0.67%) | 18 / 3127 (0.58%) | |
| occurrences causally related to treatment / all | 1 / 30 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Chronic respiratory disease | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asphyxia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Lung disorder | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung opacity | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nocturnal dyspnoea | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Platypnoea | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 8 / 3126 (0.26%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pleurisy | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 11 / 3126 (0.35%) | 9 / 3127 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 5 | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Pulmonary hilum mass | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pulmonary hypertension | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal stenosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Respiratory failure | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 17 / 3127 (0.54%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 9 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sputum retention | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Psychiatric disorders | | | |
| Delusion | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar disorder | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Completed suicide | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Confusional state | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium tremens | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Major depression | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Organic brain syndrome | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychogenic respiratory distress | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychomotor retardation | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Substance abuse | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device failure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device dislocation | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device malfunction | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device occlusion | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device power source issue | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device fastener issue | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stone | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary dilatation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 8 / 3126 (0.26%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis chronic | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congestive hepatopathy | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug-induced liver injury | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 2 / 3126 (0.06%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Hepatic failure | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hepatic mass | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic vein thrombosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis alcoholic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver disorder | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis acute | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Investigations | | | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anticoagulation drug level above therapeutic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ejection fraction decreased | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral pulse decreased | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 disease activity index abnormal | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Weight decreased | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram QRS complex prolonged | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SARS-CoV-2 antibody test positive | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SARS-CoV-2 test positive | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibrin D dimer increased | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | | | |
| Burns third degree | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Abdominal injury | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wound dehiscence | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula site complication | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back injury | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain contusion | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 10 / 3126 (0.32%) | 11 / 3127 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Comminuted fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Compression fracture | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery restenosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary bypass stenosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eschar | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical vertebral fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple fractures | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fractured sacrum | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Heat illness | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 1 / 10 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Humerus fracture | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated incisional hernia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Forearm fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Open fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patella fracture | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Penis injury | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periprosthetic fracture | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Post procedural complication | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural hypotension | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural myocardial infarction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural swelling | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic pain | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Procedural pain | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pneumothorax | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius fracture | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haemothorax | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | |
| Skin laceration | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |
| subjects affected / exposed | 11 / 3126 (0.35%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord injury | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic rupture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Stomal hernia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haematoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3126 (0.13%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Tendon rupture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haematoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Repetitive strain injury | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic intracranial haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulna fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft stenosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft thrombosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound haemorrhage | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | | | |
| Congenital hypercoagulation | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patent ductus arteriosus | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal arteriovenous malformation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Arrhythmia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Acute left ventricular failure | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 16 / 3127 (0.51%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 63 / 3126 (2.02%) | 63 / 3127 (2.01%) | |
| occurrences causally related to treatment / all | 3 / 73 | 0 / 71 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 8 | |
| Acute right ventricular failure | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina pectoris | | | |
| subjects affected / exposed | 18 / 3126 (0.58%) | 19 / 3127 (0.61%) | |
| occurrences causally related to treatment / all | 0 / 20 | 1 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |
| subjects affected / exposed | 49 / 3126 (1.57%) | 62 / 3127 (1.98%) | |
| occurrences causally related to treatment / all | 1 / 56 | 0 / 75 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve incompetence | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Arrhythmia supraventricular | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorder | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Atrial flutter | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial tachycardia | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial thrombosis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 7 / 3126 (0.22%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular dissociation | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradyarrhythmia | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 11 / 3126 (0.35%) | 13 / 3127 (0.42%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block left | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac amyloidosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 18 / 3126 (0.58%) | 17 / 3127 (0.54%) | |
| occurrences causally related to treatment / all | 1 / 18 | 0 / 17 | |
| deaths causally related to treatment / all | 1 / 17 | 0 / 15 | |
| Atrial fibrillation | | | |

| | | |
|---|--------------------|---------------------|
| subjects affected / exposed | 69 / 3126 (2.21%) | 57 / 3127 (1.82%) |
| occurrences causally related to treatment / all | 2 / 82 | 1 / 62 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardiac failure | | |
| subjects affected / exposed | 308 / 3126 (9.85%) | 377 / 3127 (12.06%) |
| occurrences causally related to treatment / all | 10 / 458 | 5 / 581 |
| deaths causally related to treatment / all | 1 / 61 | 0 / 61 |
| Cardiac failure acute | | |
| subjects affected / exposed | 57 / 3126 (1.82%) | 63 / 3127 (2.01%) |
| occurrences causally related to treatment / all | 2 / 73 | 2 / 90 |
| deaths causally related to treatment / all | 1 / 7 | 0 / 4 |
| Cardiac failure chronic | | |
| subjects affected / exposed | 23 / 3126 (0.74%) | 26 / 3127 (0.83%) |
| occurrences causally related to treatment / all | 3 / 32 | 3 / 44 |
| deaths causally related to treatment / all | 1 / 5 | 0 / 5 |
| Cardiac failure congestive | | |
| subjects affected / exposed | 63 / 3126 (2.02%) | 82 / 3127 (2.62%) |
| occurrences causally related to treatment / all | 1 / 86 | 5 / 116 |
| deaths causally related to treatment / all | 0 / 5 | 0 / 18 |
| Cardiac failure high output | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardiac valve disease | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardiorenal syndrome | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardio-respiratory arrest | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 3 / 3126 (0.10%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 5 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 9 / 3126 (0.29%) | 12 / 3127 (0.38%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 12 | |
| deaths causally related to treatment / all | 0 / 6 | 1 / 8 | |
| Cardiomegaly | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiomyopathy alcoholic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 3 | |
| Cardiac ventricular thrombosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiovascular insufficiency | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Mitral valve disease | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Chronic left ventricular failure | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congestive cardiomyopathy | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 9 / 3126 (0.29%) | 14 / 3127 (0.45%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery stenosis | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Frederick's syndrome | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart valve incompetence | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive cardiomyopathy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ischaemic cardiomyopathy | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 2 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 8 / 3127 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Microvascular coronary artery disease | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve calcification | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic coronary syndrome | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 15 / 3126 (0.48%) | 18 / 3127 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 12 | |
| Myocardial fibrosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Myxomatous mitral valve degeneration | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodal rhythm | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Right ventricular failure | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinoatrial block | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |

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|---|------------------|-------------------|--|
| subjects affected / exposed | 9 / 3126 (0.29%) | 11 / 3127 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |
| subjects affected / exposed | 8 / 3126 (0.26%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve stenosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachyarrhythmia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachycardia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachycardia induced cardiomyopathy | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Torsade de pointes | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trifascicular block | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 1 / 6 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 4 | 1 / 2 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 13 / 3126 (0.42%) | 13 / 3127 (0.42%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ataxia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bell's palsy | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain oedema | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Brain stem infarction | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery thrombosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral arteriosclerosis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haematoma | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Embolic cerebral infarction | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Drop attacks | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolic stroke | | | |
| subjects affected / exposed | 7 / 3126 (0.22%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depressed level of consciousness | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cubital tunnel syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cognitive disorder | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical cord compression | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular disorder | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Cerebral infarction | | | |
| subjects affected / exposed | 11 / 3126 (0.35%) | 11 / 3127 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 4 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Lacunar infarction | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Focal dyscognitive seizures | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lacunar stroke | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised tonic-clonic seizure | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic stroke | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 9 / 3127 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 4 | |
| Hemiparesis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic encephalopathy | | | |

| | | |
|---|-------------------|-------------------|
| subjects affected / exposed | 3 / 3126 (0.10%) | 0 / 3127 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 |
| Hypoaesthesia | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Hypoxic-ischaemic encephalopathy | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 |
| Intracranial haematoma | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Ischaemic cerebral infarction | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Ischaemic stroke | | |
| subjects affected / exposed | 70 / 3126 (2.24%) | 65 / 3127 (2.08%) |
| occurrences causally related to treatment / all | 1 / 76 | 3 / 70 |
| deaths causally related to treatment / all | 0 / 17 | 0 / 15 |
| Presyncope | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 1 / 3127 (0.03%) |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Myelopathy | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Quadripareisis | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myoclonic epilepsy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myoclonus | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myxoedema coma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinson's disease | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Parkinsonism | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Partial seizures | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral sensorimotor neuropathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy alcoholic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post stroke epilepsy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombotic stroke | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic encephalopathy | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombotic cerebral infarction | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thalamic infarction | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 18 / 3126 (0.58%) | 21 / 3127 (0.67%) | |
| occurrences causally related to treatment / all | 0 / 18 | 1 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiculopathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Spondylitic myelopathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal stroke | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tremor | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trigeminal neuralgia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uraemic encephalopathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar stroke | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular encephalopathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia Alzheimer's type | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia macrocytic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia | | | |
| subjects affected / exposed | 16 / 3126 (0.51%) | 24 / 3127 (0.77%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Blood loss anaemia | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic cyst | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deficiency anaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disseminated intravascular coagulation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Evans syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypochromic anaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocoagulable state | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microcytic anaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrogenic anaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normocytic anaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulopathy | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Meniere's disease | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tinnitus | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Epiretinal membrane | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glaucoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lens dislocation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Age-related macular degeneration | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amaurosis fugax | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blindness | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular rupture | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal artery occlusion | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal detachment | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual impairment | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous opacities | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Chronic gastritis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute abdomen | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Anal haemorrhage | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterovesical fistula | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 8 / 3127 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erosive duodenitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal vascular malformation haemorrhagic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric perforation | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric polyps | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis haemorrhagic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 14 / 3126 (0.45%) | 15 / 3127 (0.48%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Gastrointestinal motility disorder | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal necrosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal perforation | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastrointestinal polyp haemorrhage | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric antral vascular ectasia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoperitoneum | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic erosive gastritis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileal perforation | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired gastric emptying | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated umbilical hernia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia strangulated | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haemorrhage | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Haematemesis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haematoma | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haemorrhage | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic enteritis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine polyp | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 11 / 3127 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Mechanical ileus | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric haemorrhage | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive pancreatitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal obstruction | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal varices haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic duct dilatation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Tooth impacted | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 / 3126 (0.00%) | 1 / 3127 (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 | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis necrotising | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Rectal polyp | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retching | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland calculus | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strangulated umbilical hernia | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress ulcer | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3126 (0.13%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Volvulus | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cutaneous vasculitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug eruption | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erythema | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin necrosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin ulcer | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous emphysema | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Obstructive nephropathy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute kidney injury | | | |
| subjects affected / exposed | 54 / 3126 (1.73%) | 63 / 3127 (2.01%) | |
| occurrences causally related to treatment / all | 10 / 64 | 8 / 78 | |
| deaths causally related to treatment / all | 1 / 4 | 0 / 3 | |
| Calculus urinary | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 12 / 3126 (0.38%) | 10 / 3127 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 12 | 2 / 12 | |
| deaths causally related to treatment / all | 0 / 1 | 1 / 2 | |
| Cystitis glandularis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End stage renal disease | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |
| subjects affected / exposed | 5 / 3126 (0.16%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy toxic | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyuria | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal amyloidosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal colic | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst ruptured | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 9 / 3126 (0.29%) | 11 / 3127 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Renal haemorrhage | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 7 / 3126 (0.22%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Renal injury | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary fistula | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract inflammation | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | 0 / 3126 (0.00%) | 2 / 3127 (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 | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Goitre | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|------------------|------------------|--|
| Axial spondyloarthritis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mobility decreased | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical spinal stenosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis pyrophosphate | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Compartment syndrome | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gouty arthritis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemarthrosis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic osteoarthropathy | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immobilisation syndrome | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 7 / 3126 (0.22%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myositis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal synovial cyst | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 9 / 3126 (0.29%) | 8 / 3127 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondrosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis of jaw | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pathological fracture | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyarthritis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal pain | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal stenosis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oligoarthritis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tenosynovitis stenosans | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (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 | | | |
| Abdominal sepsis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess limb | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acinetobacter sepsis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute endocarditis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 6 / 3127 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis perforated | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial prostatitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial pyelonephritis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary tract infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 8 / 3126 (0.26%) | 12 / 3127 (0.38%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bullous erysipelas | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gangrene | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 35 / 3126 (1.12%) | 22 / 3127 (0.70%) | |
| occurrences causally related to treatment / all | 2 / 44 | 0 / 30 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis infective | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Complicated appendicitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronavirus infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronavirus pneumonia | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Cystitis | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis bacterial | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis escherichia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related sepsis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis infective | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis intestinal perforated | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Endocarditis bacterial | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis enterococcal | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Enterococcal sepsis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia sepsis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Furuncle | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 7 / 3126 (0.22%) | 8 / 3127 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helicobacter gastritis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster disseminated | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected skin ulcer | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Infectious pleural effusion | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Infective exacerbation of bronchiectasis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (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 | 4 / 3126 (0.13%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Intestinal gangrene | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Kidney infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella sepsis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periodontitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection bacterial | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung abscess | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lymph node tuberculosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ophthalmic herpes zoster | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 7 / 3126 (0.22%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Osteomyelitis chronic | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreas infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic abscess | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic inflammatory disease | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pyelonephritis chronic | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 113 / 3126 (3.61%) | 106 / 3127 (3.39%) | |
| occurrences causally related to treatment / all | 1 / 123 | 2 / 129 | |
| deaths causally related to treatment / all | 0 / 20 | 0 / 17 | |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 7 / 3126 (0.22%) | 8 / 3127 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3126 (0.10%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prosthetic valve endocarditis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (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 | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonsillar abscess | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus bronchitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Tuberculosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Sepsis | | | |
| subjects affected / exposed | 16 / 3126 (0.51%) | 20 / 3127 (0.64%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 12 | |
| Septic phlebitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 17 / 3126 (0.54%) | 17 / 3127 (0.54%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 13 | 0 / 12 | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin infection | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Spontaneous bacterial peritonitis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Staphylococcal bacteraemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal infection | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular abscess | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 8 / 3126 (0.26%) | 11 / 3127 (0.35%) | |
| occurrences causally related to treatment / all | 1 / 8 | 2 / 12 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral myositis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral pericarditis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval cellulitis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 2 / 3126 (0.06%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Wound sepsis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 40 / 3126 (1.28%) | 33 / 3127 (1.06%) | |
| occurrences causally related to treatment / all | 4 / 49 | 6 / 34 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asymptomatic COVID-19 | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 24 / 3126 (0.77%) | 23 / 3127 (0.74%) | |
| occurrences causally related to treatment / all | 1 / 25 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| COVID-19 | | | |
| subjects affected / exposed | 183 / 3126 (5.85%) | 144 / 3127 (4.61%) | |
| occurrences causally related to treatment / all | 3 / 187 | 0 / 147 | |
| deaths causally related to treatment / all | 0 / 23 | 0 / 16 | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 86 / 3126 (2.75%) | 89 / 3127 (2.85%) | |
| occurrences causally related to treatment / all | 0 / 86 | 1 / 91 | |
| deaths causally related to treatment / all | 0 / 42 | 0 / 36 | |
| HIV infection | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis C | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis E | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Middle East respiratory syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 17 / 3126 (0.54%) | 16 / 3127 (0.51%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 7 | 0 / 5 | |
| Metabolism and nutrition disorders | | | |
| Hyperkalaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 11 / 3126 (0.35%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 2 / 12 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cachexia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calciphylaxis | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 8 / 3127 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 6 | 2 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 14 / 3126 (0.45%) | 18 / 3127 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 17 | 2 / 18 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 3 / 3126 (0.10%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gout | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3126 (0.13%) | 4 / 3127 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 6 / 3126 (0.19%) | 7 / 3127 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypernatraemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic syndrome | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 9 / 3126 (0.29%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 10 / 3126 (0.32%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 7 / 3126 (0.22%) | 8 / 3127 (0.26%) | |
| occurrences causally related to treatment / all | 1 / 7 | 2 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoproteinaemia | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 4 / 3126 (0.13%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ketosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 0 / 3127 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactic acidosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Latent autoimmune diabetes in adults | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 3126 (0.00%) | 1 / 3127 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Marasmus | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 2 / 3127 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 1 / 3126 (0.03%) | 5 / 3127 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 3 / 3127 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 3126 (0.00%) | 10 / 3127 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 2 %

| Non-serious adverse events | Dapa 10 mg | Placebo | |
|---|---------------------|---------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 464 / 3126 (14.84%) | 485 / 3127 (15.51%) | |
| Vascular disorders | | | |
| Hypotension | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 69 / 3126 (2.21%) | 61 / 3127 (1.95%) | |
| occurrences (all) | 80 | 68 | |
| Hypertension | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 84 / 3126 (2.69%) | 102 / 3127 (3.26%) | |
| occurrences (all) | 104 | 136 | |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 86 / 3126 (2.75%) | 61 / 3127 (1.95%) | |
| occurrences (all) | 103 | 70 | |
| Cardiac failure | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 179 / 3126 (5.73%) | 214 / 3127 (6.84%) | |
| occurrences (all) | 240 | 255 | |
| Infections and infestations | | | |
| Urinary tract infection | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 113 / 3126 (3.61%) | 112 / 3127 (3.58%) | |
| occurrences (all) | 142 | 128 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|-------------------------------------|
| 09 May 2018 | Clinical Study Protocol Version 2.0 |
| 16 December 2019 | Clinical Study Protocol Version 3.0 |
| 20 November 2020 | Clinical Study Protocol Version 4.0 |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported