# Clinical trial results:
# A phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The dal-GenE trial

## Summary

| | |
|---|---|
| EudraCT number | 2015-003895-65 |
| Trial protocol | NL BE SE SK DK FI PT DE HU ES AT CZ BG RO PL GB IT |
| Global end of trial date | 23 June 2021 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 24 September 2022 |
| First version publication date | 24 September 2022 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | DAL-301 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02525939 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | DalCor Pharma UK Ltd. |
| Sponsor organisation address | Leatherhead, Swiss Branch, Zug Baarerstrasse 2, Zug, Switzerland, CH-6302 |
| Public contact | Donald M. Black, DalCor Pharma, Dblack@dalcorpharma.com |
| Scientific contact | Donald M. Black, DalCor Pharma, Dblack@dalcorpharma.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 | 20 May 2022 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 23 June 2021 |
| Global end of trial reached? | Yes |
| Global end of trial date | 23 June 2021 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this trial is to evaluate the potential of dalcetrapib to reduce cardiovascular morbidity and mortality (cardiovascular death, resuscitated cardiac arrest, non-fatal myocardial infarction (MI) and non-fatal stroke) in subjects with a documented recent ACS and the AA genotype at variant rs1967309 in the ADCY9 gene.

Protection of trial subjects:

All considerations regarding the protection of human subjects were carried out in accordance with the protocol, GCP, ICH Guidelines, the ethical principles that have their origin in the Declaration of Helsinki, and all applicable regulatory requirements. The investigator (according to applicable regulatory requirements) or a person designated by the investigator and under the investigator's responsibility fully informed patients of all pertinent aspects of the clinical trial.

Background therapy:

Dalcetrapib and matching placebo were taken on a background of contemporary evidence-based medical care for status post-ACS, as individually prescribed by the treating physician.

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 13 April 2016 |
| 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 | Israel: 373 |
| Country: Number of subjects enrolled | Russian Federation: 455 |
| Country: Number of subjects enrolled | Switzerland: 36 |
| Country: Number of subjects enrolled | Turkey: 57 |
| Country: Number of subjects enrolled | United Arab Emirates: 16 |
| Country: Number of subjects enrolled | Australia: 202 |
| Country: Number of subjects enrolled | New Zealand: 150 |
| Country: Number of subjects enrolled | Argentina: 148 |
| Country: Number of subjects enrolled | Brazil: 431 |
| Country: Number of subjects enrolled | Canada: 437 |
| Country: Number of subjects enrolled | United States: 728 |
| Country: Number of subjects enrolled | Chile: 94 |
| Country: Number of subjects enrolled | South Africa: 222 |
| Country: Number of subjects enrolled | Puerto Rico: 14 |
| Country: Number of subjects enrolled | Netherlands: 276 |

| | |
|---|---|
| Country: Number of subjects enrolled | Poland: 335 |
| Country: Number of subjects enrolled | Portugal: 54 |
| Country: Number of subjects enrolled | Romania: 179 |
| Country: Number of subjects enrolled | Slovakia: 48 |
| Country: Number of subjects enrolled | Spain: 188 |
| Country: Number of subjects enrolled | Sweden: 66 |
| Country: Number of subjects enrolled | United Kingdom: 382 |
| Country: Number of subjects enrolled | Austria: 50 |
| Country: Number of subjects enrolled | Belgium: 39 |
| Country: Number of subjects enrolled | Bulgaria: 384 |
| Country: Number of subjects enrolled | Czechia: 152 |
| Country: Number of subjects enrolled | Denmark: 137 |
| Country: Number of subjects enrolled | Finland: 20 |
| Country: Number of subjects enrolled | France: 99 |
| Country: Number of subjects enrolled | Germany: 69 |
| Country: Number of subjects enrolled | Hungary: 183 |
| Country: Number of subjects enrolled | Italy: 123 |
| Worldwide total number of subjects | 6147 |
| EEA total number of subjects | 2402 |

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) | 3711 |
| From 65 to 84 years | 2397 |
| 85 years and over | 39 |

## Subject disposition

### Recruitment

Recruitment details:

Screening procedures were performed at the time of the index ACS event or anytime thereafter, with the condition that the randomization window must have occurred within the mandated window (1 to 3 months after the index event).

### Pre-assignment

Screening details:

Subjects were assessed based on their medical history. Those who were likely to qualify were consented, had a blood test obtained, and underwent a cobas® ADCY9 Genotype Clinical Trial Assay. Those patients who met the genetic testing criteria, all the other inclusion criteria, and none of the exclusion criteria were eligible for randomization.

### Period 1

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

Blinding implementation details:

The blind during the study was maintained by administration of 2 matching placebo tablets to patients in the placebo group. Furthermore, the project teams of DalCor, the CROs, as well as the Investigator and his or her study personnel were blinded with respect to levels of HDL-C so as not to reveal patients' assignment to 1 of the 2 treatment groups. Levels of triglycerides (TG) and LDL-C values were not blinded to allow for appropriate patient management.

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Dalcetrapib 600 mg |

Arm description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day.
Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

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

Dosage and administration details:

Dalcetrapib was provided as film-coated tablets of 300 mg.
Patients received 600 mg of dalcetrapib (2 tablets) once daily. Study medication was taken with food, preferably with the largest meal of the day. Patients were instructed to take study medication with the same meal throughout the study.
Study medication kits were dispensed at every visit. Study medication was packaged in boxes containing 7 bottles each. Each bottle contained study medication for one month, i.e., 60 pills (2 x 300 mg tablets per day). A box thus contained study medication for 7 months.

| | |
|---|---|
| **Arm title** | Placebo 600 mg |

Arm description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day.
The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

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

Dosage and administration details:

Matching placebo was provided as film-coated tablets of 300 mg.
Patients received 600 mg of matching placebo (2 tablets) once daily. Study medication was taken with food, preferably with the largest meal of the day. Patients were instructed to take study medication with the same meal throughout the study.
Study medication kits were dispensed at every visit. Study medication was packaged in boxes containing 7 bottles each. Each bottle contained study medication for one month, i.e., 60 pills (2 x 300 mg tablets per day). A box thus contained study medication for 7 months.

| **Number of subjects in period 1** | Dalcetrapib 600 mg | Placebo 600 mg |
|---|---|---|
| Started | 3071 | 3076 |
| Completed | 2840 | 2833 |
| Not completed | 231 | 243 |
| Adverse event, serious fatal | 180 | 179 |
| Consent withdrawn by subject | 24 | 39 |
| Physician decision | - | 1 |
| Lost to follow-up | 27 | 24 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Dalcetrapib 600 mg |

Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day.
Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

| Reporting group title | Placebo 600 mg |
|---|---|

Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day.
The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

| Reporting group values | Dalcetrapib 600 mg | Placebo 600 mg | Total |
|---|---|---|---|
| Number of subjects | 3071 | 3076 | 6147 |
| Age categorical<br>Units: Subjects | | | |
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | <br><br>62.19<br>± 9.16 | <br><br>62.34<br>± 9.25 | <br><br><br>- |
| Gender categorical<br>Units: Subjects | | | |
| Female | 723 | 672 | 1395 |
| Male | 2348 | 2404 | 4752 |

## End points

### End points reporting groups

| Reporting group title | Dalcetrapib 600 mg |
|---|---|

Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event).
Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day.
Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

| Reporting group title | Placebo 600 mg |
|---|---|

Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event).
Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day.
The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

### Primary: Primary endpoint

| End point title | Primary endpoint |
|---|---|

End point description:

The primary endpoint of this study was the time from randomization to first occurrence of any component of the composite event as adjudicated by the Clinical Endpoints Committee (CEC).
Components of the primary composite were cardiovascular (CV) death, resuscitated cardiac arrest, non-fatal myocardial infarction (MI) and non-fatal stroke.
Time to event (or censoring) was calculated as the difference (in days) between the randomization date and the date of first occurrence of an adjudicated event (or censoring date in patients without event) plus 1 day.
One patient population was used for analysis of data for this study, the Intent-to-Treat (ITT) population.
A stratified Cox proportional hazards model was used to analyze the primary endpoint.

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

End point timeframe:

There was no minimum or maximum study treatment duration defined for this study, but the expected overall duration was 54 months including recruitment and follow-up.

| End point values | Dalcetrapib 600 mg | Placebo 600 mg | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3071 | 3076 | | |
| Units: patients | 3071 | 3076 | | |

## Statistical analyses

| Statistical analysis title | Cox proportional hazards model |
|---|---|

Statistical analysis description:

A stratified Cox proportional hazards model was used to analyze the primary endpoint. Time to event started at randomization and subjects who were event-free were censored at the time that they were last known to be event-free. The null and alternative hypotheses tested with the above Cox model were: H0: $\lambda = 1$ versus. HA: $\lambda \neq 1$, where $\lambda$ is the, assumed constant, HR for the time to occurrence of the composite events of the primary endpoint for the dalcetrapib and placebo treated groups.

| | |
|---|---|
| Comparison groups | Dalcetrapib 600 mg v Placebo 600 mg |
| Number of subjects included in analysis | 6147 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.12 |
| Method | Stratified Cox proportional hazards mode |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.75 |
| upper limit | 1.03 |
| Variability estimate | Standard deviation |

## Secondary: Secondary endpoint-1

| End point title | Secondary endpoint-1 |
|---|---|

End point description:

Time to first Occurrence of any component of the composite endpoint of CV death, resuscitated cardiac arrest, non-fatal MI, non-fatal stroke, hospitalization for ACS (with ECG abnormalities) or unanticipated coronary revascularization
Time to event (or censoring) was calculated as the difference (in days) between the randomization date and the date of first occurrence of an adjudicated event (or censoring date in patients without event) plus 1 day.
One patient population was used for analysis of data for this study, the Intent-to-Treat (ITT) population.

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

End point timeframe:

There was no minimum or maximum study treatment duration defined for this study, but the expected overall duration was 54 months including recruitment and follow-up.

| End point values | Dalcetrapib 600 mg | Placebo 600 mg | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3071 | 3076 | | |
| Units: patients | 3071 | 3076 | | |

### Statistical analyses

| Statistical analysis title | Cox proportional hazards model |
|---|---|

Statistical analysis description:

A stratified Cox proportional hazards model was used to analyze the primary endpoint. Time to event started at randomization and subjects who were event-free were censored at the time that they were last known to be event-free. The null and alternative hypotheses tested with the above Cox model were: H0: $\lambda = 1$ versus. HA: $\lambda \neq 1$, where $\lambda$ is the, assumed constant, HR for the time to occurrence of the composite events of the secondary endpoint for the dalcetrapib and placebo treated groups

| | |
|---|---|
| Comparison groups | Placebo 600 mg v Dalcetrapib 600 mg |
| Number of subjects included in analysis | 6147 |
| Analysis specification | Pre-specified |
| Analysis type | other[1] |
| P-value | = 0.945 [2] |
| Method | Stratified Cox proportional hazards mode |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.88 |
| upper limit | 1.13 |
| Variability estimate | Standard deviation |

Notes:

[1] - Cox proportional hazards model

[2] - Results demonstrated that patients with the AA genotype at variant rs1967309 in the ADCY9 gene experienced no reduction in the risk for any component of the composite endpoint.

### Secondary: Secondary endpoint-2

| End point title | Secondary endpoint-2 |
|---|---|

End point description:

Time to first occurrence of any component of the composite endpoint of CV death, resuscitated cardiac arrest, non-fatal MI, non-fatal stroke or hospitalization for new or worsening heart failure.
Time to event (or censoring) was calculated as the difference (in days) between the randomization date and the date of first occurrence of an adjudicated event (or censoring date in patients without event) plus 1 day.
One patient population was used for analysis of data for this study, the Intent-to-Treat (ITT) population.
A stratified Cox proportional hazards model was used to analyze the primary endpoint.

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

End point timeframe:

There was no minimum or maximum study treatment duration defined for this study, but the expected overall duration was 54 months including recruitment and follow-up.

| End point values | Dalcetrapib 600 mg | Placebo 600 mg | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3071 | 3076 | | |
| Units: patients | 3071 | 3076 | | |

## Statistical analyses

| Statistical analysis title | Cox proportional hazards model |
|---|---|

Statistical analysis description:

A stratified Cox proportional hazards model was used to analyze the primary endpoint. Time to event started at randomization and subjects who were event-free were censored at the time that they were last known to be event-free. The null and alternative hypotheses tested with the above Cox model were: H0: $\lambda = 1$ versus. HA: $\lambda \neq 1$, where $\lambda$ is the, assumed constant, HR for the time to occurrence of the composite events of the secondary endpoint for the dalcetrapib and placebo treated groups.

| | |
|---|---|
| Comparison groups | Dalcetrapib 600 mg v Placebo 600 mg |
| Number of subjects included in analysis | 6147 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.27 [3] |
| Method | Stratified Cox proportional hazards mode |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.07 |
| Variability estimate | Standard deviation |

Notes:

[3] - Treatment with dalcetrapib failed to meet the pre-specified threshold for a positive outcome in regards to the secondary endpoint-2.

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse event monitoring starts from the time the patient consents to the study until they complete the trial

Adverse event reporting additional description:

A Treatment-emergent adverse event (TEAE) was defined as an adverse event (AE) that occurred on or after the administration of the first dose of study drug.

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 19.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Placebo 600 mg |

Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Matching placebo was provided as 300 mg film-coated tablets. Patients received 600 mg of matching placebo (2 tablets) once daily, preferably with the largest meal of the day.
The placebo was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

| | |
|---|---|
| Reporting group title | Dalcetrapib 600 mg |

Reporting group description:

Patients recently hospitalized for an ACS (between 1 month and 3 months after the index event). Dalcetrapib was provided as 300 mg film-coated tablets. Patients received 600 mg of dalcetrapib (2 tablets) once daily, preferably with the largest meal of the day.
Dalcetrapib was taken on a background of contemporary evidence-based medical care for ACS, including aspirin, clopidogrel, beta-blockers, angiotensin-converting enzyme inhibitors, and statins; and medication for optimal control of hypertension, angina, and diabetes. Patients were allowed to reduce dose to 300 mg once daily or temporarily interrupt study drug as deemed necessary due to physician assessment.
Patients visited the clinic 1 month and 6 months after randomization and every 6 months thereafter. The study lasted until approximately 582 patients experienced a primary event, at which time the sites were contacted and asked to bring their patients in for final visits.

| **Serious adverse events** | Placebo 600 mg | Dalcetrapib 600 mg | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 923 / 3076 (30.01%) | 900 / 3071 (29.31%) | |
| number of deaths (all causes) | 179 | 180 | |
| number of deaths resulting from adverse events | 133 | 127 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Abdominal neoplasm | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute leukaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of colon | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Anal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atypical fibroxanthoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign lung neoplasm | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of prostate | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of thyroid gland | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 6 / 3071 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer metastatic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer stage II | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cancer pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carcinoid tumour | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Chest wall tumour | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholesteatoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia stage 1 | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon adenoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Colon cancer stage IV | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon neoplasm | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diffuse large B-cell lymphoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial sarcoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Epstein-Barr virus associated lymphoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Extranodal marginal zone B-cell lymphoma (MALT type) | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Giant cell tumour of tendon sheath | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Glioma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hepatic cancer recurrent | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hodgkin's disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Intestinal adenocarcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal cancer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Laryngeal papilloma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leiomyoma | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip and/or oral cavity cancer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung adenocarcinoma metastatic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma stage III | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung cancer metastatic | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lung neoplasm malignant | | | |

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|---|---|---|---|
| subjects affected / exposed | 5 / 3076 (0.16%) | 6 / 3071 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 3 | |
| Lymphoma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant melanoma in situ | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant polyp | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to adrenals | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastases to liver | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to lung | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Metastases to lymph nodes | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic carcinoma of the bladder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastatic neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastatic renal cell carcinoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myeloproliferative neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Neoplasm malignant | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma metastatic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine tumour | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer metastatic | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Oesophageal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Oesophageal carcinoma | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian epithelial cancer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | |
| Pancreatic carcinoma metastatic | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Parathyroid tumour benign | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma cell myeloma recurrent | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polycythaemia vera | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 27 / 3076 (0.88%) | 10 / 3071 (0.33%) | |
| occurrences causally related to treatment / all | 1 / 28 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Prostate cancer recurrent | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer stage I | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal cancer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer metastatic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Small intestine carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (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 | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Thyroid cancer | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell cancer of the renal pelvis and ureter | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Tumour haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteral neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Aortic aneurysm rupture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic dissection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic intramural haematoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stenosis | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial insufficiency | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial perforation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial stenosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Arteritis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure inadequately controlled | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism arterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 1 / 10 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 6 / 3071 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemic shock | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermittent claudication | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Internal haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lymphocele | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant hypertension | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral embolism | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phlebitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (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 | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thromboangiitis obliterans | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis superficial | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vasculitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Aneurysm repair | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angioplasty | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthrodesis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atherectomy | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure management | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone lesion excision | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ablation | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac pacemaker insertion | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac pacemaker replacement | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac rehabilitation therapy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac resynchronisation therapy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract operation | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystectomy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithotomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colostomy closure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary angioplasty | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary arterial stent insertion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery bypass | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary revascularisation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Finger amputation | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart transplant | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatectomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia repair | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip arthroplasty | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implantable defibrillator insertion | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Insertion of ambulatory peritoneal catheter | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Keratoplasty | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Knee arthroplasty | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left atrial appendage occlusion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb amputation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lithotripsy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device change | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmic fluid drainage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ossiculoplasty | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Percutaneous coronary intervention | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rehabilitation therapy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal transplant | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue flap operation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stem cell transplant | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth extraction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tumour excision | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral dilation procedure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitrectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac death | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 79 / 3076 (2.57%) | 81 / 3071 (2.64%) | |
| occurrences causally related to treatment / all | 0 / 93 | 0 / 104 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 17 / 3071 (0.55%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 17 | |
| Drowning | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Drug intolerance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exercise tolerance decreased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired self-care | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodule | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-cardiac chest pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 28 / 3076 (0.91%) | 41 / 3071 (1.34%) | |
| occurrences causally related to treatment / all | 0 / 40 | 0 / 45 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pacemaker generated arrhythmia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyp | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| 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 | 3 / 3076 (0.10%) | 8 / 3071 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 8 | |
| Sudden death | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 16 / 3071 (0.52%) | |
| occurrences causally related to treatment / all | 0 / 14 | 1 / 16 | |
| deaths causally related to treatment / all | 0 / 14 | 1 / 16 | |
| Systemic inflammatory response syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent restenosis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food allergy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoidosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |

| | | | |
|---|---|---|---|
| Alcohol use | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sight disability | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 9 / 3071 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|---|---|
| Uterine polyp | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal prolapse | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 6 / 3071 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 8 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 1 / 1 | |
| Aspiration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiectasis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|---|---|
| Bronchitis chronic | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchopneumopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchospasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bullous lung disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 19 / 3076 (0.62%) | 15 / 3071 (0.49%) | |
| occurrences causally related to treatment / all | 0 / 34 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 16 / 3071 (0.52%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |

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|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 8 / 3071 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal granuloma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infiltration | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal obstruction | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-cardiogenic pulmonary oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary congestion | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory acidosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 8 / 3071 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 3 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord polyp | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Alcohol abuse | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphasia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional state | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conversion disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Depression | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hallucinations, mixed | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mania | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic stress disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizoaffective disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Somatic symptom disorder | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Substance abuse | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device dislocation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device material issue | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Acute hepatic failure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct obstruction | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis acute | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 8 / 3071 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 8 / 3071 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis chronic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug-induced liver injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cyst | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic lesion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis toxic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice cholestatic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-alcoholic steatohepatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Angiogram | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriogram coronary | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biopsy prostate | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood folate decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac murmur | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac stress test abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid bruit | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheterisation cardiac | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheterisation cardiac abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystoscopy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diagnostic procedure | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ejection fraction decreased | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibrin D dimer increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Occult blood positive | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic enzymes increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep study | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcus test positive | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress echocardiogram abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteroscopy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (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 | | | |
| Alcohol poisoning | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic complication | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic leak | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial bypass thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial restenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stenosis traumatic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical vertebral fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Comminuted fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery restenosis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costal cartilage fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Electric shock | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Extradural haematoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye burns | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 11 / 3071 (0.36%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stoma complication | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria traumatic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incomplete spinal fusion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Intentional overdose | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple injuries | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Overdose | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery restenosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirenal haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural bile leak | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural discomfort | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Postoperative respiratory failure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural nausea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory fume inhalation disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Snake bite | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |

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|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stab wound | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sternal fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haematoma | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (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 | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| 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 | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention postoperative | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound dehiscence | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound secretion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Atrial septal defect | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bicuspid aortic valve | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocele | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|---|---|
| Adams-Stokes syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina pectoris | | | |
| subjects affected / exposed | 50 / 3076 (1.63%) | 52 / 3071 (1.69%) | |
| occurrences causally related to treatment / all | 0 / 55 | 0 / 53 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Angina unstable | | | |
| subjects affected / exposed | 23 / 3076 (0.75%) | 19 / 3071 (0.62%) | |
| occurrences causally related to treatment / all | 0 / 24 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve incompetence | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriospasm coronary | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 36 / 3076 (1.17%) | 31 / 3071 (1.01%) | |
| occurrences causally related to treatment / all | 1 / 47 | 0 / 35 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial flutter | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial tachycardia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac aneurysm | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 5 | |
| Cardiac failure | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Cardiac failure acute | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiac failure chronic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac tamponade | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac valve disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ventricular thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 4 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiovascular insufficiency | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Carditis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cor pulmonale | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Coronary artery disease | | | |

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|---|---|---|---|
| subjects affected / exposed | 23 / 3076 (0.75%) | 30 / 3071 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 31 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Coronary artery dissection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery perforation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery stenosis | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic cardiomyopathy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular dysfunction | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Long QT syndrome | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 12 / 3071 (0.39%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Myocarditis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Right ventricular failure | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sinus arrest | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular extrasystoles | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systolic dysfunction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachycardia | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 8 / 3071 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Nervous system disorders** | | | |
| Balance disorder | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery disease | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral artery stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haematoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Cerebral ischaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical radiculopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicobrachial syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cognitive disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Dementia Alzheimer's type | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidotic hyperglycaemic coma | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disturbance in attention | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Guillain-Barre syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocephalus | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic coma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxic-ischaemic encephalopathy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar radiculopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbosacral radiculopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Memory impairment | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monoparesis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuralgia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |

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|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radicular pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 28 / 3076 (0.91%) | 24 / 3071 (0.78%) | |
| occurrences causally related to treatment / all | 1 / 33 | 0 / 28 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 6 / 3071 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tremor | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular dementia | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral artery stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar insufficiency | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Blood and lymphatic system disorders** | | | |
| Anaemia | | | |
| subjects affected / exposed | 21 / 3076 (0.68%) | 19 / 3071 (0.62%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypochromic anaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Hodgkin's lymphoma recurrent | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic haematoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic infarction | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic vein thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Ear canal stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniere's disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tinnitus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |

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|---|---|---|---|
| Blindness transient | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Optic nerve disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal detachment | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal tear | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinopathy of prematurity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual acuity reduced | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma pancreas | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fissure | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Auriculotemporal syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coeliac artery stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 2 | 2 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Functional gastrointestinal disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer perforation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis haemorrhagic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal angiodysplasia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| 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 | 8 / 3076 (0.26%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastrointestinal necrosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | | | |

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|---|---|---|---|
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gingival recession | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.03%) | 0 / 3071 (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 | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernial eventration | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiatus hernia | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus paralytic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory bowel disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 5 / 3076 (0.16%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia strangulated | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haemorrhage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal ischaemia | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine polyp | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mallory-Weiss syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric panniculitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal dysplasia | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 6 / 3071 (0.20%) | |
| occurrences causally related to treatment / all | 1 / 16 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal venous gas | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haematoma | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subileus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Volvulus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin lesion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin mass | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Swelling face | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Xanthelasma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Renal and urinary disorders** | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 20 / 3076 (0.65%) | 18 / 3071 (0.59%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Anuria | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder dysplasia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus bladder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urinary | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 13 / 3071 (0.42%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage urinary tract | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Micturition disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvi-ureteric obstruction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proteinuria | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 9 / 3071 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune thyroiditis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cushing's syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperparathyroidism primary | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid mass | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic goitre | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis reactive | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 9 / 3076 (0.29%) | 4 / 3071 (0.13%) | | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Cervical spinal stenosis | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Chondrocalcinosis pyrophosphate | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Facet joint syndrome | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Foot deformity | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Gouty arthritis | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Intervertebral disc degeneration | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Intervertebral disc disorder | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | | |
| Intervertebral disc protrusion | | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 6 / 3071 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint effusion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Knee impingement syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb deformity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mobility decreased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle twitching | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 9 / 3076 (0.29%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 27 / 3076 (0.88%) | 23 / 3071 (0.75%) | |
| occurrences causally related to treatment / all | 0 / 29 | 0 / 25 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteolysis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoporosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | | | |

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|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in jaw | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column stenosis | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal pain | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral osteophyte | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 abscess | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess limb | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess of salivary gland | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess oral | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis perforated | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerotic gangrene | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial infection | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary sepsis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain abscess | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac valve vegetation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 12 / 3071 (0.39%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis staphylococcal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Central nervous system infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis infective | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic abscess | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Corona virus infection | | | |
| subjects affected / exposed | 43 / 3076 (1.40%) | 45 / 3071 (1.47%) | |
| occurrences causally related to treatment / all | 0 / 44 | 0 / 45 | |
| deaths causally related to treatment / all | 0 / 15 | 0 / 11 | |
| Creutzfeldt-Jakob disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cystitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Device related infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot infection | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema infected | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Empyema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Endocarditis bacterial | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymitis | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia pyelonephritis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer helicobacter | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis bacterial | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 10 / 3076 (0.33%) | 8 / 3071 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 10 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma infection | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemophilus bacteraemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helicobacter infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (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 | 1 / 3076 (0.03%) | 0 / 3071 (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 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster oticus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected lymphocele | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious colitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective exacerbation of bronchiectasis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective exacerbation of chronic obstructive airways disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella bacteraemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella sepsis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung abscess | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenic sepsis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nosocomial infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmic herpes simplex | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreas infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirectal abscess | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (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 | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 41 / 3076 (1.33%) | 39 / 3071 (1.27%) | |
| occurrences causally related to treatment / all | 0 / 50 | 0 / 45 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 3 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia escherichia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia legionella | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia necrotising | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia staphylococcal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Postoperative wound infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 7 / 3071 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis chronic | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory tract infection bacterial | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal abscess | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 19 / 3076 (0.62%) | 14 / 3071 (0.46%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 4 | |
| Septic shock | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 10 / 3071 (0.33%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 4 | |
| Serratia bacteraemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shunt infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 17 / 3071 (0.55%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Vestibular neuronitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Adult failure to thrive | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes with hyperosmolarity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic metabolic decompensation | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gout | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperosmolar hyperglycaemic state | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 3076 (0.16%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactic acidosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Obesity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| **Non-serious adverse events** | Placebo 600 mg | Dalcetrapib 600 mg | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 2363 / 3076 (76.82%) | 2380 / 3071 (77.50%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acanthoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Acrochordon | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Adenoma benign | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Adrenal adenoma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Anogenital warts | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Atypical fibroxanthoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 26 / 3071 (0.85%) | |
| occurrences (all) | 22 | 27 | |
| Basosquamous carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Benign breast neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Benign gastrointestinal neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Benign lymph node neoplasm | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Benign neoplasm of skin | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Benign neoplasm of thyroid gland | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Benign salivary gland neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bowen's disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Breast adenoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Breast cancer metastatic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Breast cancer recurrent | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Breast neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bronchial neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Carcinoid tumour | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Chronic lymphocytic leukaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Colon adenoma | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 9 | 8 | |
| Colon neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Dysplastic naevus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Enchondromatosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fibroadenoma of breast | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fibrous histiocytoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Haemangioma of liver | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Haemangioma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Haemangioma of skin | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hodgkin's disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypergammaglobulinaemia benign | | | |

| | | | |
|---|---|---|---|
| monoclonal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Keratoacanthoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Kidney angiomyolipoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Large intestine benign neoplasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Laryngeal cancer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Leiomyoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lentigo maligna | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Lip squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Lipoma | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Lung carcinoma cell type unspecified stage IV | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 3 | 8 | |
| Malignant melanoma in situ | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Melanocytic naevus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 0 | 4 | |
| Metastases to bone | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Metastases to lung | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Metastases to thorax | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Monoclonal gammopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Neoplasm malignant | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Neoplasm skin | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Neuroma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Ocular neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Oral papilloma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pancreatic carcinoma metastatic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pancreatic neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Papilloma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pituitary tumour benign | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Plasma cell myeloma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pleural mesothelioma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polycythaemia vera | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Prostate cancer | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 8 | 5 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Prostate cancer recurrent | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Prostatic adenoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Pyogenic granuloma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rectal cancer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rectal neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Salivary gland neoplasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Seborrhoeic keratosis | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 7 | 6 | |
| Skin cancer | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 5 | 2 | |
| Skin papilloma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Small cell lung cancer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 10 | 5 | |

| | | | |
|---|---|---|---|
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tonsil cancer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Vulval cancer stage 0 | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vulval cancer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vascular disorders | | | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Angiopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Angiosclerosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 8 | 9 | |
| Aortic calcification | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Aortic arteriosclerosis | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Aortic dilatation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 1 | 4 | |
| Aortic dissection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Aortic stenosis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Aortic thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Arterial disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 6 | |
| Arteriosclerosis Moenckeberg-type | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arteritis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Behcet's syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Blood pressure fluctuation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 6 | |
| Blood pressure inadequately controlled | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Brachiocephalic arteriosclerosis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Brachiocephalic vein stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Capillary fragility | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Carotid arteriosclerosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Circulatory collapse | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Diastolic hypertension | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Dry gangrene | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

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|---|---|---|---|
| Embolism | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Embolism venous | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Embolism arterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Flushing | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Haematoma | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 19 | 18 | |
| Haemorrhage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Hot flush | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 9 | 6 | |
| Hypertension | | | |
| subjects affected / exposed | 266 / 3076 (8.65%) | 277 / 3071 (9.02%) | |
| occurrences (all) | 312 | 322 | |
| Hypertensive angiopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 18 / 3076 (0.59%) | 24 / 3071 (0.78%) | |
| occurrences (all) | 25 | 25 | |
| Hypotension | | | |
| subjects affected / exposed | 73 / 3076 (2.37%) | 78 / 3071 (2.54%) | |
| occurrences (all) | 75 | 82 | |
| Intermittent claudication | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 6 | 15 | |

| | | | |
|---|---|---|---|
| Ischaemia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Jugular vein thrombosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Labile blood pressure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Labile hypertension | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Lymphoedema | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Non-dipping | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Orthostatic hypertension | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 21 / 3076 (0.68%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 21 | 14 | |
| Perineal haematoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 7 | 8 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |

| | | | |
|---|---|---|---|
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Peripheral coldness | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Peripheral ischaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Peripheral venous disease | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 6 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 2 | 5 | |
| Phlebitis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Poor peripheral circulation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Presyncope | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Raynaud's phenomenon | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 5 | 6 | |
| Shock | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Subclavian artery stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Subclavian steal syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Temporal arteritis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Thrombophlebitis superficial | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Thrombosed varicose vein | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Varicose ulceration | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Varicose vein | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 6 | 8 | |
| Vasculitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vasospasm | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vasodilatation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Venous thrombosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| **Surgical and medical procedures** | | | |
| Abdominal cavity drainage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Abdominal hernia repair | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abscess drainage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Acrochordon excision | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Angioplasty | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Aortic surgery | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Aortic valve replacement | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Appendicectomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Arterial stent insertion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arthrodesis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Arthrotomy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Blepharoplasty | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Breast prosthesis implantation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bunion operation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Cardiac ablation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cardiac pacemaker battery replacement | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiac pacemaker replacement | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cardiac pacemaker insertion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiac rehabilitation therapy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiac resynchronisation therapy | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Cardioversion | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Carotid endarterectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Carpal tunnel decompression | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Cataract operation | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 24 / 3071 (0.78%) | |
| occurrences (all) | 16 | 31 | |
| Chemotherapy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cholecystectomy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Circumcision | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Corneal transplant | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Coronary angioplasty | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Coronary artery bypass | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Coronary revascularisation | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 6 | 9 | |
| Cyst removal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dental implantation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Dental operation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Dermatofibroma removal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Drain placement | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Elective surgery | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Endodontic procedure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Endovenous ablation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Foot operation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastrointestinal endoscopic therapy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Glaucoma surgery | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hernia repair | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Hip arthroplasty | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Hip surgery | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hospitalisation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

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|---|---|---|---|---|
| Implantable cardiac monitor insertion | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| Implantable defibrillator insertion | | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | | |
| occurrences (all) | 2 | 3 | | |
| Incisional drainage | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Inguinal hernia repair | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | | |
| occurrences (all) | 1 | 2 | | |
| Intestinal polypectomy | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Joint debridement | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Knee arthroplasty | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 2 | | |
| Knee operation | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Large intestinal polypectomy | | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | | |
| occurrences (all) | 3 | 5 | | |
| Left atrial appendage occlusion | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Leg amputation | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 2 | 0 | | |
| Lens extraction | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 2 | |
| Lithotripsy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Mass excision | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Meniscus removal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Mole excision | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Osteosynthesis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Osteotomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Percutaneous coronary intervention | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 4 | 5 | |
| Peripheral nerve decompression | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Peripheral nerve transposition | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Polypectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 1 | 4 | |
| Post procedural drainage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Postoperative care | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Prostatic operation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pterygium operation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pulmonary resection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rectal polypectomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Removal of internal fixation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Retinal laser coagulation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rotator cuff repair | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Skin graft | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin lesion excision | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Skin neoplasm excision | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 2 | |
| Small intestinal anastomosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Spinal fusion surgery | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Spinal laminectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Splenectomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Stent placement | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Suprapubic prostatectomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Suture insertion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tendon sheath incision | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Thyroidectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Toe amputation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tooth extraction | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 12 | 14 | |
| Tooth repair | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Trabeculectomy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tracheostomy | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Transurethral prostatectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Umbilical hernia repair | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Ureteral stent insertion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Urethral dilation procedure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urethrotomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Uterine prolapse repair | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Varicose vein operation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 4 | |
| Vitrectomy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| General disorders and administration site conditions | | | |
| Administration site extravasation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Adverse drug reaction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 5 | |
| Adverse reaction | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Application site pruritus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Asthenia | | | |
| subjects affected / exposed | 32 / 3076 (1.04%) | 45 / 3071 (1.47%) | |
| occurrences (all) | 33 | 47 | |
| Catheter site haematoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Catheter site pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Catheter site phlebitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 38 / 3076 (1.24%) | 49 / 3071 (1.60%) | |
| occurrences (all) | 41 | 53 | |
| Chest pain | | | |
| subjects affected / exposed | 239 / 3076 (7.77%) | 268 / 3071 (8.73%) | |
| occurrences (all) | 295 | 334 | |
| Chills | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Crepitations | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cyst | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 6 | 4 | |
| Discomfort | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Drug withdrawal syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Drug intolerance | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Dysplasia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Early satiety | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Exercise tolerance decreased | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 6 | 4 | |
| Face oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Facial pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fat necrosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fatigue | | | |
| subjects affected / exposed | 101 / 3076 (3.28%) | 115 / 3071 (3.74%) | |
| occurrences (all) | 104 | 123 | |
| Feeling cold | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Feeling abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Feeling drunk | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Feeling hot | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Feeling jittery | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Feeling of body temperature change | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| General symptom | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Haemorrhagic cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hernia | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Hernia pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hunger | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Hypothermia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Impaired healing | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Implant site haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Implant site pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Implant site swelling | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Induration | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Inflammation | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Influenza like illness | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 13 / 3071 (0.42%) | |
| occurrences (all) | 21 | 16 | |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Injection site haematoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injection site haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Local swelling | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Malaise | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 12 / 3076 (0.39%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 12 | 7 | |
| Mass | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Medical device site pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Mucosal inflammation | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Nodule | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 75 / 3076 (2.44%) | 66 / 3071 (2.15%) | |
| occurrences (all) | 96 | 82 | |
| Oedema | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 6 | 10 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 60 / 3076 (1.95%) | 62 / 3071 (2.02%) | |
| occurrences (all) | 62 | 65 | |
| Pain | | | |
| subjects affected / exposed | 25 / 3076 (0.81%) | 19 / 3071 (0.62%) | |
| occurrences (all) | 26 | 20 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 20 / 3076 (0.65%) | 21 / 3071 (0.68%) | |
| occurrences (all) | 21 | 21 | |
| Polyp | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Postoperative fever | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pyrexia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 24 / 3076 (0.78%) | 21 / 3071 (0.68%) | |
| occurrences (all) | 24 | 22 | |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Swelling | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Ulcer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vaccination site reaction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Vascular stent restenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vascular stent stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vessel puncture site bruise | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Immune system disorders | | | |
| Allergic oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Allergy to arthropod sting | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |

| | | | |
|---|---|---|---|
| Allergy to arthropod bite | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Amyloidosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Contrast media allergy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 8 | 4 | |
| Food allergy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 13 | 8 | |
| Immunisation reaction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sarcoidosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 9 | 1 | |
| Seasonal allergy | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 8 | 8 | |
| Social circumstances | | | |
| Menopause | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Poor personal hygiene | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Stress at work | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tobacco user | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Treatment noncompliance | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Vascular device user | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 36 / 3076 (1.17%) | 36 / 3071 (1.17%) | |
| occurrences (all) | 37 | 36 | |
| Breast calcifications | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Breast cyst | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Breast mass | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 1 | 4 | |
| Breast pain | | | |

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|---|---|---|---|
| subjects affected / exposed | 4 / 3076 (0.13%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Breast tenderness | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Breast ulceration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cervical cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cervical dysplasia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cervix disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cystocele | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Ejaculation failure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Endometrial thickening | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Epididymal cyst | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Erectile dysfunction | | | |
| subjects affected / exposed | 35 / 3076 (1.14%) | 34 / 3071 (1.11%) | |
| occurrences (all) | 35 | 34 | |
| Fibrocystic breast disease | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Genital atrophy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Genital discomfort | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Genital hypoaesthesia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Genital prolapse | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Genital rash | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Gynaecomastia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 3 | 6 | |
| Haematospermia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Hydrocele female | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Menorrhagia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Metrorrhagia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Pelvic pain | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Penile pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Peyronie's disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Postmenopausal haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Prostatic obstruction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Prostatism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 1 | 5 | |
| Prostatitis | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 8 | 10 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 6 | 7 | |
| Pruritus genital | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Rectocele | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Retrograde ejaculation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Scrotal swelling | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Sexual dysfunction | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Testicular atrophy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Testicular mass | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Testicular pain | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Uterine polyp | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Vaginal prolapse | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Varicocele | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Vulvovaginal discomfort | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vulvovaginal dryness | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute pulmonary oedema | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Aphonia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Apnoea | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Aspiration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Asthma | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 13 | 15 | |
| Asthmatic crisis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Atelectasis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Bendopnoea | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bronchial obstruction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bronchiectasis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 5 | 2 | |
| Bronchitis chronic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 6 | |
| Bronchospasm | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Catarrh | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 48 / 3076 (1.56%) | 29 / 3071 (0.94%) | |
| occurrences (all) | 57 | 47 | |
| Cough | | | |
| subjects affected / exposed | 95 / 3076 (3.09%) | 140 / 3071 (4.56%) | |
| occurrences (all) | 101 | 159 | |
| Dry throat | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dysphonia | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 12 | 3 | |
| Dyspnoea | | | |
| subjects affected / exposed | 155 / 3076 (5.04%) | 152 / 3071 (4.95%) | |
| occurrences (all) | 168 | 171 | |
| Dyspnoea at rest | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 59 / 3076 (1.92%) | 40 / 3071 (1.30%) | |
| occurrences (all) | 59 | 41 | |
| Dyspnoea paroxysmal nocturnal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |

| | | | |
|---|---|---|---|
| Emphysema | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 4 | 7 | |
| Eosinophilic bronchitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 46 / 3076 (1.50%) | 55 / 3071 (1.79%) | |
| occurrences (all) | 58 | 67 | |
| Haemoptysis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 4 | 11 | |
| Hiccups | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Hydrothorax | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Hyperventilation | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Increased bronchial secretion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Increased upper airway secretion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Laryngeal oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |

| | | | |
|---|---|---|---|
| Laryngeal ulceration | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Laryngospasm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Lung cyst | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Lung infiltration | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Nasal discomfort | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Nasal congestion | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 7 | 9 | |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Nasal polyps | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Nasal turbinate abnormality | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nocturnal dyspnoea | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 20 / 3071 (0.65%) | |
| occurrences (all) | 6 | 22 | |

| | | | |
|---|---|---|---|
| Painful respiration | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Paranasal sinus discomfort | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pharyngeal paraesthesia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Pharyngeal lesion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pleural adhesion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pleural effusion | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 12 | 6 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Pneumothorax | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Productive cough | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 8 | 6 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |

| | | | |
|---|---|---|---|
| Pulmonary haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Pulmonary infarction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 10 | 19 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Pulmonary pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Reflux laryngitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Respiration abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Respiratory acidosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory disorder | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 6 | 3 | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory muscle weakness | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Respiratory failure | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Respiratory symptom | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 5 | |
| Respiratory tract inflammation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 15 | 11 | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 5 | 1 | |
| Rhonchi | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Sinus disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Sinus polyp | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 33 / 3076 (1.07%) | 28 / 3071 (0.91%) | |
| occurrences (all) | 33 | 28 | |
| Sneezing | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Sputum increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Throat irritation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Wheezing | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 6 | 6 | |
| Psychiatric disorders | | | |
| Abnormal behaviour | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Abnormal dreams | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Adjustment disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Adjustment disorder with mixed anxiety and depressed mood | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Affect lability | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Affective disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Aggression | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Agitation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 2 | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Alcoholism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Anger | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Anxiety | | | |
| subjects affected / exposed | 50 / 3076 (1.63%) | 56 / 3071 (1.82%) | |
| occurrences (all) | 53 | 58 | |
| Anxiety disorder | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 2 | 6 | |
| Apathy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Attention deficit/hyperactivity disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Binge drinking | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Bruxism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Burnout syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Claustrophobia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Confusional state | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 4 | 7 | |
| Delirium | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 5 | 6 | |
| Depressed mood | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Depression | | | |
| subjects affected / exposed | 56 / 3076 (1.82%) | 55 / 3071 (1.79%) | |
| occurrences (all) | 60 | 56 | |
| Disorientation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Drug dependence | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eating disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Emotional disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Generalised anxiety disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Hallucination | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Impulsive behaviour | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Initial insomnia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Insomnia | | | |
| subjects affected / exposed | 36 / 3076 (1.17%) | 53 / 3071 (1.73%) | |
| occurrences (all) | 40 | 55 | |
| Irritability | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Libido decreased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Loss of libido | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Major depression | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Mental fatigue | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Mental status changes | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Mood altered | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Mood swings | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

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|---|---|---|---|
| Nervousness | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Nightmare | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 3 | |
| Obsessive-compulsive disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Panic attack | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Panic disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Panic reaction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Persecutory delusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polydipsia psychogenic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Post-traumatic stress disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Rapid eye movement sleep behaviour disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Restlessness | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Sleep disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 6 | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Stress | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 4 | 7 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Product issues | | | |
| Device breakage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Device dislocation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Device failure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Device issue | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Device malfunction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Device material opacification | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Device stimulation issue | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Product difficult to swallow | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |

| | | | |
|---|---|---|---|
| Hepatobiliary disorders | | | |
| Alcoholic liver disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bile duct obstruction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bile duct stone | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Biliary cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Biliary dyskinesia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Biloma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cholecystitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 22 / 3076 (0.72%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 22 | 12 | |
| Cholecystitis chronic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Cholecystitis acute | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cholestasis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gallbladder enlargement | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Gallbladder polyp | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Hepatic cirrhosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Hepatic cyst | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Hepatic lesion | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Hepatic mass | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 12 | 9 | |
| Hepatic pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hepatocellular injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Hepatomegaly | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Hepatosplenomegaly | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Ischaemic hepatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Liver disorder | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Non-alcoholic fatty liver | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 6 | 4 | |
| Angiogram | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Anticoagulation drug level below therapeutic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Antinuclear antibody | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Antinuclear antibody positive | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arteriogram coronary | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 5 | |
| Arthroscopy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Aspiration pleural cavity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Biopsy liver | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Biopsy prostate | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Biopsy skin normal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Biopsy stomach abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bleeding time prolonged | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |

| | | | |
|---|---|---|---|
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Blood calcium increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood cholesterol increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Blood creatine increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood creatine phosphokinase abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 15 | 10 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 13 | 15 | |
| Blood folate decreased | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Blood glucose abnormal | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Blood glucose fluctuation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood glucose increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 3076 (0.20%) | 18 / 3071 (0.59%) | |
| occurrences (all) | 6 | 18 | |
| Blood iron decreased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Blood lactic acid increased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Blood magnesium decreased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 1 | 7 | |
| Blood potassium decreased | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 7 | 6 | |
| Blood potassium increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Blood pressure abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Blood pressure decreased | | | |
| subjects affected / exposed | 38 / 3076 (1.24%) | 36 / 3071 (1.17%) | |
| occurrences (all) | 43 | 38 | |
| Blood pressure diastolic decreased | | | |
| subjects affected / exposed | 36 / 3076 (1.17%) | 36 / 3071 (1.17%) | |
| occurrences (all) | 40 | 41 | |
| Blood pressure diastolic increased | | | |
| subjects affected / exposed | 48 / 3076 (1.56%) | 31 / 3071 (1.01%) | |
| occurrences (all) | 50 | 32 | |
| Blood pressure difference of extremities | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood pressure increased | | | |
| subjects affected / exposed | 71 / 3076 (2.31%) | 59 / 3071 (1.92%) | |
| occurrences (all) | 79 | 70 | |

| | | | | |
|---|---|---|---|---|
| Blood pressure orthostatic | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Blood pressure systolic decreased | | | | |
| subjects affected / exposed | 61 / 3076 (1.98%) | 51 / 3071 (1.66%) | | |
| occurrences (all) | 65 | 55 | | |
| Blood pressure systolic increased | | | | |
| subjects affected / exposed | 64 / 3076 (2.08%) | 54 / 3071 (1.76%) | | |
| occurrences (all) | 65 | 58 | | |
| Blood test abnormal | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Blood testosterone decreased | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| Blood thyroid stimulating hormone abnormal | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Blood thyroid stimulating hormone decreased | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| Blood thyroid stimulating hormone increased | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | | |
| occurrences (all) | 0 | 2 | | |
| Blood triglycerides | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Blood triglycerides increased | | | | |
| subjects affected / exposed | 20 / 3076 (0.65%) | 12 / 3071 (0.39%) | | |
| occurrences (all) | 22 | 12 | | |
| Blood urea increased | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | | |
| occurrences (all) | 0 | 3 | | |
| Blood uric acid increased | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Blood urine present | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Body temperature increased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Brain natriuretic peptide increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Breath sounds | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Breath sounds abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| C-reactive protein abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 18 / 3076 (0.59%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 18 | 15 | |
| Cardiac imaging procedure abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Cardiac murmur | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Cardiac stress test abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Carotid bruit | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Catheterisation cardiac | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Chest X-ray abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Colonoscopy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Computerised tomogram thorax abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Cystoscopy | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 8 | 2 | |
| Echocardiogram abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ejection fraction decreased | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Electrocardiogram P wave abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Electrocardiogram PR prolongation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Electrocardiogram T wave amplitude decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Electrocardiogram T wave inversion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Electrocardiogram abnormal | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Electrocardiogram change | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Faecal calprotectin increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fibrin D dimer increased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 2 | 5 | |
| Fractional flow reserve | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Free prostate-specific antigen increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Functional residual capacity decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Glomerular filtration rate abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Glomerular filtration rate decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 4 | |
| Glucose tolerance increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Glycosylated haemoglobin increased | | | |
| subjects affected / exposed | 21 / 3076 (0.68%) | 18 / 3071 (0.59%) | |
| occurrences (all) | 22 | 18 | |
| Grip strength decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| HIV test positive | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 6 | 14 | |
| Heart rate abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Heart rate decreased | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 5 | 17 | |
| Heart rate increased | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 7 | 15 | |
| Heart rate irregular | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Helicobacter test positive | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 10 | 9 | |
| High density lipoprotein decreased | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| International normalised ratio | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Intraocular pressure increased | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Laboratory test abnormal | | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | | |
| occurrences (all) | 3 | 4 | | |
| Lipids increased | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| Liver function test abnormal | | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | | |
| occurrences (all) | 5 | 7 | | |
| Liver function test increased | | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | | |
| occurrences (all) | 5 | 5 | | |
| Low density lipoprotein decreased | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| Low density lipoprotein increased | | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 7 / 3071 (0.23%) | | |
| occurrences (all) | 5 | 8 | | |
| Mammogram abnormal | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| N-terminal prohormone brain natriuretic peptide increased | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| Norovirus test positive | | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 2 | 0 | | |

| | | | |
|---|---|---|---|
| Occult blood | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Occult blood positive | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Oesophagogastroduodenoscopy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Optic nerve cup/disc ratio increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Oxygen saturation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oxygen saturation decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Pancreatic enzymes increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pedal pulse decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Platelet count decreased | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 2 | |
| Positron emission tomogram abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Precancerous cells present | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Prohormone brain natriuretic peptide increased | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Prostatic specific antigen increased | | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 9 / 3071 (0.29%) | | |
| occurrences (all) | 9 | 9 | | |
| Pulse absent | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| QRS axis abnormal | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Radial pulse abnormal | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Radioisotope scan | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Serum ferritin decreased | | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | | |
| occurrences (all) | 3 | 3 | | |
| Serum ferritin increased | | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | | |
| occurrences (all) | 2 | 3 | | |
| Single photon emission computerised tomogram abnormal | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Streptococcus test positive | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Stress echocardiogram abnormal | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Thyroid function test abnormal | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |

| | | | |
|---|---|---|---|
| Transaminases increased | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Treponema test | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Troponin T increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Troponin increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Ultrasound Doppler abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ultrasound prostate abnormal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Ureteroscopy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Urine albumin/creatinine ratio increased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Vital functions abnormal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vitamin B12 decreased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Vitamin D decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Weight decreased | | | |
| subjects affected / exposed | 23 / 3076 (0.75%) | 27 / 3071 (0.88%) | |
| occurrences (all) | 25 | 27 | |
| Weight increased | | | |
| subjects affected / exposed | 19 / 3076 (0.62%) | 25 / 3071 (0.81%) | |
| occurrences (all) | 19 | 25 | |
| White blood cell count increased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Alcohol poisoning | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Anaemia postoperative | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Anastomotic ulcer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Animal bite | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Ankle fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 2 | 6 | |
| Arthropod sting | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Arthropod bite | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 3 | 8 | |
| Back injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 2 | 6 | |
| Bone contusion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cartilage injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cervical vertebral fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Chemical burns of eye | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Chest injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Chillblains | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Concussion | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 3 | 6 | |
| Contusion | | | |
| subjects affected / exposed | 37 / 3076 (1.20%) | 50 / 3071 (1.63%) | |
| occurrences (all) | 41 | 54 | |
| Corneal abrasion | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Costal cartilage fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Cystitis radiation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dislocation of vertebra | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Electric shock | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Epicondylitis | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 6 | 9 | |
| Eschar | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Excoriation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eye injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Eyelid injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Face injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Facial bones fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Fall | | | |
| subjects affected / exposed | 40 / 3076 (1.30%) | 40 / 3071 (1.30%) | |
| occurrences (all) | 44 | 44 | |
| Fibula fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Foot fracture | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 13 | 7 | |
| Forearm fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Foreign body | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Foreign body in eye | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Fracture displacement | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 2 | |
| Gun shot wound | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 6 | 11 | |
| Head injury | | | |

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|---|---|---|---|
| subjects affected / exposed | 8 / 3076 (0.26%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 8 | 4 | |
| Hip fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Immunisation reaction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Incision site haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Incisional hernia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Injury | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Injury corneal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Joint dislocation | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 4 | 5 | |
| Joint injury | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 7 | 9 | |
| Laceration | | | |
| subjects affected / exposed | 21 / 3076 (0.68%) | 23 / 3071 (0.75%) | |
| occurrences (all) | 21 | 23 | |
| Ligament injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Ligament rupture | | | |

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|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Ligament sprain | | | |
| subjects affected / exposed | 20 / 3076 (0.65%) | 27 / 3071 (0.88%) | |
| occurrences (all) | 20 | 28 | |
| Limb crushing injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Limb injury | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 21 / 3071 (0.68%) | |
| occurrences (all) | 18 | 21 | |
| Limb traumatic amputation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Medication error | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Meniscus injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 2 | 7 | |
| Mouth injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Multiple fractures | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Muscle injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Muscle rupture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Muscle strain | | | |
| subjects affected / exposed | 19 / 3076 (0.62%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 21 | 14 | |
| Musculoskeletal injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Nasal injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Nerve injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Oesophageal injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Overdose | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Patella fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Peripheral artery restenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Peroneal nerve injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Post concussion syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Post procedural constipation | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Post procedural fistula | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Post-traumatic pain | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Post-traumatic neck syndrome | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Postoperative ileus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Postoperative thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Postoperative wound complication | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Procedural dizziness | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Procedural hypotension | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Procedural pain | | | |

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|---|---|---|---|
| subjects affected / exposed | 9 / 3076 (0.29%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 9 | 1 | |
| Procedural vomiting | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Radiation pneumonitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Radius fracture | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 6 | 3 | |
| Rib fracture | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 8 | 12 | |
| Road traffic accident | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 2 | 7 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Scratch | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 0 | 7 | |
| Skull fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Soft tissue injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 1 | 6 | |
| Spinal column injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Spinal compression fracture | | | |

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|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Spinal fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sternal fracture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Stress fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Subcutaneous haematoma | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sunburn | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Synovial rupture | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tendon injury | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Tendon rupture | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 9 | 9 | |
| Thermal burn | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Thoracic vertebral fracture | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tooth fracture | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Tooth injury | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Traumatic arthritis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Traumatic haematoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ulnar nerve injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper limb fracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 2 | 8 | |
| Vaccination complication | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 0 | 4 | |
| Vascular access site pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Vascular pseudoaneurysm thrombosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Wound | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 9 | 10 | |
| Wound complication | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Wound dehiscence | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Wound haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Wound secretion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Wrist fracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| XIIth nerve injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Congenital, familial and genetic disorders | | | |
| Atrial septal defect | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Congenital coronary artery malformation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Congenital megaureter | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Congenital lip fistula | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Dolichocolon | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gilbert's syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Heart disease congenital | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hereditary haemochromatosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hydrocele | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Myotonic dystrophy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Phimosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Porokeratosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rathke's cleft cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Thyroglossal cyst | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Angina pectoris | | | |
| subjects affected / exposed | 114 / 3076 (3.71%) | 109 / 3071 (3.55%) | |
| occurrences (all) | 125 | 130 | |

| | | | |
|---|---|---|---|
| Angina unstable | | | |
| subjects affected / exposed | 13 / 3076 (0.42%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 14 | 11 | |
| Anginal equivalent | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Aortic valve calcification | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Aortic valve incompetence | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Aortic valve sclerosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Arrhythmia supraventricular | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Arrhythmia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Arteriospasm coronary | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 2 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 70 / 3076 (2.28%) | 56 / 3071 (1.82%) | |
| occurrences (all) | 84 | 66 | |
| Atrial flutter | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 11 | 5 | |
| Atrial thrombosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |

| | | | |
|---|---|---|---|
| Atrial tachycardia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 34 / 3076 (1.11%) | 26 / 3071 (0.85%) | |
| occurrences (all) | 36 | 27 | |
| Bundle branch block left | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bundle branch block right | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 7 | 2 | |
| Cardiac failure | | | |
| subjects affected / exposed | 26 / 3076 (0.85%) | 33 / 3071 (1.07%) | |
| occurrences (all) | 27 | 35 | |
| Cardiac failure chronic | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 6 | 2 | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 9 | 11 | |
| Cardiac failure acute | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiac flutter | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |

| | | | |
|---|---|---|---|
| Cardiac ventricular thrombosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 1 | 5 | |
| Cardiac valve disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cardiomegaly | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Cardiovascular disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Chest pain | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Chronic left ventricular failure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Chronotropic incompetence | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Conduction disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Congestive cardiomyopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 2 | |

| | | | |
|---|---|---|---|
| Coronary artery disease | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 7 | 9 | |
| Coronary artery stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Diastolic dysfunction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 3 | |
| Dilatation atrial | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Extrasystoles | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Heart valve incompetence | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Hepatojugular reflux | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Intracardiac thrombus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ischaemic cardiomyopathy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Left ventricular dysfunction | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 6 | 2 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |

| | | | |
|---|---|---|---|
| Left ventricular hypertrophy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Mitral valve calcification | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Mitral valve incompetence | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Myocarditis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 5 | 8 | |
| Nodal arrhythmia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Palpitations | | | |
| subjects affected / exposed | 66 / 3076 (2.15%) | 50 / 3071 (1.63%) | |
| occurrences (all) | 70 | 55 | |
| Pericarditis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 0 | 6 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Prinzmetal angina | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

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|---|---|---|---|
| Right ventricular failure | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sinoatrial block | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 10 | 7 | |
| Sinus node dysfunction | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 3 | 11 | |
| Supraventricular extrasystoles | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 7 | 8 | |
| Tachycardia | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 13 | 11 | |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 5 | 2 | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 16 / 3076 (0.52%) | 16 / 3071 (0.52%) | |
| occurrences (all) | 17 | 16 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |

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|---|---|---|---|
| Ventricular hypokinesia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Ventricular remodelling | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 8 | 8 | |
| Wolff-Parkinson-White syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Ageusia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Amnesia | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 13 / 3071 (0.42%) | |
| occurrences (all) | 8 | 13 | |
| Anosmia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Aphasia | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Aphonia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Ataxia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Autonomic nervous system imbalance | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Balance disorder | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 5 | |
| Burning sensation | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Carotid arteriosclerosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Carotid artery aneurysm | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Carotid artery disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Carotid artery insufficiency | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Carotid artery stenosis | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 9 | 4 | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 17 | 13 | |
| Cerebellar artery thrombosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cerebellar microhaemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cerebral arteriosclerosis | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Cerebral atrophy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cerebral disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cerebral haematoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Cerebral microhaemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cerebrovascular disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cervical myelopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cervical radiculopathy | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 5 | 1 | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cluster headache | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cognitive disorder | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 6 | 2 | |

| | | | |
|---|---|---|---|
| Cubital tunnel syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dementia | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 6 | 5 | |
| Dementia Alzheimer's type | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Demyelination | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Diabetic neuropathy | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 11 | 8 | |
| Disturbance in attention | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Dizziness | | | |
| subjects affected / exposed | 138 / 3076 (4.49%) | 147 / 3071 (4.79%) | |
| occurrences (all) | 151 | 166 | |
| Dizziness exertional | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Dizziness postural | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 9 | 8 | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Dysarthria | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Dysgeusia | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 10 | 8 | |

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|---|---|---|---|---|
| Dyskinesia | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Encephalopathy | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Enlarged cerebral perivascular spaces | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Epilepsy | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Essential tremor | | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 2 | 0 | | |
| Extrapyramidal disorder | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Facial neuralgia | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Facial paralysis | | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | | |
| occurrences (all) | 5 | 3 | | |
| Freezing phenomenon | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Head discomfort | | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 3 | 1 | | |
| Headache | | | | |
| subjects affected / exposed | 96 / 3076 (3.12%) | 142 / 3071 (4.62%) | | |
| occurrences (all) | 115 | 165 | | |
| Hemianaesthesia | | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hemiparesis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 5 | 1 | |
| Hemiplegia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hydrocephalus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 27 / 3076 (0.88%) | 36 / 3071 (1.17%) | |
| occurrences (all) | 30 | 36 | |
| Hypogeusia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hyposmia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Hypotonia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| IIIrd nerve paralysis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| IVth nerve paralysis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Intercostal neuralgia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Intracranial mass | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Lethargy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 3076 (0.20%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 7 | 9 | |
| Leukoencephalopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Lumbar radiculopathy | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Lumbosacral radiculopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Memory impairment | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 10 | 8 | |
| Meralgia paraesthetica | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Migraine with aura | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Migraine | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 7 | 8 | |
| Motor dysfunction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Movement disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Multiple sclerosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Myelopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Myoclonus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Nerve compression | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Nervous system disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nerve root compression | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Neuralgia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 13 / 3076 (0.42%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 13 | 12 | |
| Normal pressure hydrocephalus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Occipital neuralgia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Paraesthesia | | | |
| subjects affected / exposed | 29 / 3076 (0.94%) | 27 / 3071 (0.88%) | |
| occurrences (all) | 29 | 28 | |
| Paralysis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Paresis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Parkinson's disease | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Parkinsonism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Parosmia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Phantom pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polyneuropathy | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Post-traumatic headache | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Presyncope | | | |
| subjects affected / exposed | 19 / 3076 (0.62%) | 13 / 3071 (0.42%) | |
| occurrences (all) | 22 | 13 | |
| Pseudoradicular syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Psychomotor hyperactivity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Quadrantanopia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Radicular syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Radiculopathy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Restless legs syndrome | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 6 | 3 | |
| Sciatica | | | |
| subjects affected / exposed | 27 / 3076 (0.88%) | 27 / 3071 (0.88%) | |
| occurrences (all) | 27 | 27 | |
| Seizure | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Sinus headache | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 2 | |
| Somnolence | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Speech disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Spinal cord disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Syncope | | | |
| subjects affected / exposed | 37 / 3076 (1.20%) | 32 / 3071 (1.04%) | |
| occurrences (all) | 41 | 35 | |
| Tension headache | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Tongue biting | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Transient global amnesia | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Tremor | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 4 | 11 | |
| Trigeminal neuralgia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Ulnar neuritis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ulnar tunnel syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vascular dementia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Vertebral artery stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vertebral artery occlusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Visual field defect | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vocal cord paralysis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| White matter lesion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Blood and lymphatic system disorders | | | |

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|---|---|---|---|
| Anaemia | | | |
| subjects affected / exposed | 62 / 3076 (2.02%) | 60 / 3071 (1.95%) | |
| occurrences (all) | 65 | 62 | |
| Anaemia macrocytic | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Anaemia of chronic disease | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Anaemia vitamin B12 deficiency | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bone marrow oedema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Coagulopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Deficiency anaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eosinophilia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Haemorrhagic diathesis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Heparin-induced thrombocytopenia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hilar lymphadenopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Hypochromic anaemia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 5 | |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 18 / 3076 (0.59%) | 27 / 3071 (0.88%) | |
| occurrences (all) | 18 | 27 | |
| Leukocytosis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 3 | 8 | |
| Lymphadenopathy mediastinal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Lymphopenia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Macrocytosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Microcytic anaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Neutropenia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |

| | | | |
|---|---|---|---|
| Neutrophilia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Normochromic normocytic anaemia | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 6 | 4 | |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Pernicious anaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polycythaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Spleen disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Splenic cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Splenomegaly | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Spontaneous haematoma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 5 | 6 | |
| Thrombocytosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ear and labyrinth disorders | | | |
| Cerumen impaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 5 | |
| Deafness | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Deafness bilateral | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 5 | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Deafness unilateral | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 1 | 6 | |
| Ear discomfort | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Ear haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Ear pain | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 6 | 11 | |
| Ear pruritus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ear swelling | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eustachian tube disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eustachian tube dysfunction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Excessive cerumen production | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| External ear inflammation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Hypoacusis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 6 | |
| Inner ear disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Meniere's disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Middle ear effusion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Motion sickness | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Otorrhoea | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Presbyacusis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Sudden hearing loss | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tinnitus | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 14 | 15 | |
| Tympanic membrane perforation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Vertigo | | | |

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|---|---|---|---|
| subjects affected / exposed | 35 / 3076 (1.14%) | 30 / 3071 (0.98%) | |
| occurrences (all) | 38 | 31 | |
| Vertigo positional | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 6 | 5 | |
| Vestibular disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eye disorders | | | |
| Age-related macular degeneration | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Amaurosis fugax | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Amaurosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arteriosclerotic retinopathy | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Astigmatism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blepharitis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Blindness | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cataract nuclear | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cataract | | | |
| subjects affected / exposed | 47 / 3076 (1.53%) | 40 / 3071 (1.30%) | |
| occurrences (all) | 54 | 47 | |

| | | | |
|---|---|---|---|
| Chorioretinopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Conjunctival hyperaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 6 | |
| Conjunctival oedema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Dacryostenosis acquired | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Diabetic retinopathy | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 7 | 6 | |
| Diabetic retinal oedema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Diplopia | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 6 | 0 | |
| Dry eye | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 4 | 9 | |
| Eye allergy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eye colour change | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eye discharge | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Eye disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Eye haemorrhage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Eye inflammation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Eye irritation | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 5 | 1 | |
| Eye oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Eye pruritus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eye pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Eye swelling | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Eyelid irritation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eyelid ptosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 5 | |
| Eyelid oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 1 | 5 | |
| Foreign body sensation in eyes | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Glaucoma | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 3 | 8 | |
| Hypermetropia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hyphaema | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Idiopathic orbital inflammation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Iridocyclitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Keratitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Lacrimation increased | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Macular degeneration | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Macular fibrosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Macular hole | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Macular oedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Meibomian gland dysfunction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Meibomianitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Myopia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Neovascular age-related macular degeneration | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Ocular hyperaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Ocular hypertension | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Ocular ischaemic syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ocular vascular disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Open angle glaucoma | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Ophthalmic vein thrombosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Panophthalmitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Photophobia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Posterior capsule opacification | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Presbyopia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pterygium | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Retinal artery occlusion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Retinal degeneration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Retinal detachment | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 6 | 3 | |
| Retinal disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Retinal haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Retinal tear | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Retinal vein occlusion | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Retinopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Retinopathy hypertensive | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Scleral pigmentation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Strabismus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sudden visual loss | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Trichiasis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Ulcerative keratitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Vision blurred | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 16 | 4 | |
| Visual acuity reduced | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Visual impairment | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 2 | 5 | |
| Vitreous adhesions | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vitreous degeneration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vitreous detachment | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Vitreous floaters | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Vitreous haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 18 | 17 | |
| Abdominal distension | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 23 / 3071 (0.75%) | |
| occurrences (all) | 18 | 25 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Abdominal pain | | | |
| subjects affected / exposed | 58 / 3076 (1.89%) | 76 / 3071 (2.47%) | |
| occurrences (all) | 67 | 81 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 54 / 3076 (1.76%) | 77 / 3071 (2.51%) | |
| occurrences (all) | 57 | 89 | |
| Abdominal tenderness | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abdominal wall mass | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abnormal faeces | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 2 | 5 | |
| Anal erosion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Anal fissure | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 6 | 0 | |

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|---|---|---|---|
| Anal fistula | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Anal incontinence | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Anal pruritus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Anorectal discomfort | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Aphthous ulcer | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Ascites | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Bowel movement irregularity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Breath odour | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Burning mouth syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 5 | |
| Change of bowel habit | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |

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|---|---|---|---|
| Chronic cheek biting | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Chronic gastritis | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 6 | 5 | |
| Coeliac disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Colitis | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 6 | 3 | |
| Constipation | | | |
| subjects affected / exposed | 67 / 3076 (2.18%) | 69 / 3071 (2.25%) | |
| occurrences (all) | 71 | 75 | |
| Crohn's disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Dental caries | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 4 | 8 | |
| Diarrhoea | | | |
| subjects affected / exposed | 186 / 3076 (6.05%) | 300 / 3071 (9.77%) | |
| occurrences (all) | 220 | 378 | |
| Diarrhoea haemorrhagic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Diverticulum | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 14 | 11 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 6 | 8 | |

| | | | |
|---|---|---|---|
| Diverticulum oesophageal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Dry mouth | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 11 | 6 | |
| Duodenitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 4 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Dyschezia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 50 / 3076 (1.63%) | 58 / 3071 (1.89%) | |
| occurrences (all) | 55 | 64 | |
| Dysphagia | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 6 | 10 | |
| Eosinophilic oesophagitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Epigastric discomfort | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 4 | 5 | |
| Epiploic appendagitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Erosive oesophagitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Eructation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

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|---|---|---|---|
| Faecalith | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Faeces discoloured | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Faeces hard | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Faeces soft | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 6 | 5 | |
| Femoral hernia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Flatulence | | | |
| subjects affected / exposed | 19 / 3076 (0.62%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 19 | 15 | |
| Food poisoning | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Frequent bowel movements | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Gastric dilatation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Gastric disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 1 | 6 | |
| Gastric polyps | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Gastric mucosal lesion | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

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|---|---|---|---|
| Gastric ulcer | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 10 | 1 | |
| Gastritis | | | |
| subjects affected / exposed | 32 / 3076 (1.04%) | 21 / 3071 (0.68%) | |
| occurrences (all) | 33 | 21 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 6 | |
| Gastritis haemorrhagic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastroduodenitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Gastrointestinal angiodysplasia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Gastrointestinal disorder | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 8 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Gastrointestinal motility disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Gastrointestinal ulcer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Gastrointestinal wall thickening | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

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|---|---|---|---|
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 48 / 3076 (1.56%) | 51 / 3071 (1.66%) | |
| occurrences (all) | 50 | 51 | |
| Gastrooesophageal sphincter insufficiency | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gingival bleeding | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 5 | 6 | |
| Gingival cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Gingival pain | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Haematemesis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Haematochezia | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 16 / 3071 (0.52%) | |
| occurrences (all) | 5 | 17 | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 16 / 3076 (0.52%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 16 | 18 | |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hiatus hernia | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 10 | 12 | |
| Hyperchlorhydria | | | |

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|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Ileus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Infrequent bowel movements | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 18 | 10 | |
| Intestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Intestinal polyp | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 5 | 8 | |
| Intestinal prolapse | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 0 | 7 | |
| Large intestinal stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Large intestine polyp | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 13 | 17 | |
| Lower gastrointestinal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Lumbar hernia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Melaena | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 1 | 7 | |
| Mesenteric panniculitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Mouth ulceration | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 5 | 2 | |
| Nausea | | | |
| subjects affected / exposed | 66 / 3076 (2.15%) | 100 / 3071 (3.26%) | |
| occurrences (all) | 76 | 114 | |
| Noninfective gingivitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Odynophagia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Oesophageal discomfort | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Oesophageal food impaction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Oesophageal motility disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oesophageal spasm | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Oesophagitis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 5 | 8 | |
| Oesophagitis ulcerative | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Oral disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oral pain | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Palatal disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pancreatic atrophy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pancreatic cyst | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Pancreatic disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pancreatic steatosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Pancreatitis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Pancreatitis chronic | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Peptic ulcer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 0 | 4 | |
| Periodontal disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Periodontal inflammation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pharyngo-oesophageal diverticulum | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Poor dental condition | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Portal hypertensive gastropathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Proctitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 25 / 3076 (0.81%) | 13 / 3071 (0.42%) | |
| occurrences (all) | 25 | 13 | |
| Rectal polyp | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Rectal prolapse | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rectal stenosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Reflux gastritis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Saliva altered | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Salivary duct obstruction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Salivary gland calculus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 3 | |
| Salivary gland mass | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Salivary gland mucocoele | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Salivary hypersecretion | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Stress ulcer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Subileus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Swollen tongue | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Teeth brittle | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tongue discomfort | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tongue haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Tongue ulceration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tooth disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Tooth impacted | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Toothache | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 14 | 12 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 7 | 7 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Varices oesophageal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Vomiting | | | |
| subjects affected / exposed | 38 / 3076 (1.24%) | 33 / 3071 (1.07%) | |
| occurrences (all) | 46 | 40 | |
| Skin and subcutaneous tissue disorders | | | |

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|---|---|---|---|
| Acne | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Actinic keratosis | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 11 | 15 | |
| Alopecia | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 10 | 6 | |
| Angioedema | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Blister | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Blood blister | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bromhidrosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cold sweat | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Contusion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cutis laxa | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 6 | |
| Dermal cyst | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 4 | 8 | |

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| Dermatitis | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 12 | 5 | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 11 | 1 | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Dermatitis contact | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 7 | |
| Dermatitis herpetiformis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Diabetic foot | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Diabetic ulcer | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Diffuse alopecia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Dry skin | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 8 | 6 | |
| Dyshidrotic eczema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ecchymosis | | | |
| subjects affected / exposed | 13 / 3076 (0.42%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 13 | 13 | |

| | | | |
|---|---|---|---|
| Eczema | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 11 | 15 | |
| Eczema asteatotic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Erythema | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 9 | 14 | |
| Granulomatous dermatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Haemorrhage subcutaneous | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hair colour changes | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hair disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hand dermatitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Hidradenitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 10 | 12 | |
| Hyperkeratosis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 7 | |

| | | | |
|---|---|---|---|
| Idiopathic urticaria | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Ingrowing nail | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Intertrigo | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Lichen planus | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Lichen sclerosus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lichenoid keratosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Miliaria | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Nail discolouration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nail disorder | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Nail toxicity | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Night sweats | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 5 | 1 | |
| Onychoclasis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |

| | | | |
|---|---|---|---|
| Pain of skin | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Papule | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Parapsoriasis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Perivascular dermatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Petechiae | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pigmentation disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pityriasis rosea | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Precancerous skin lesion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pruritus | | | |
| subjects affected / exposed | 25 / 3076 (0.81%) | 35 / 3071 (1.14%) | |
| occurrences (all) | 25 | 41 | |
| Pruritus allergic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pruritus generalised | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 5 | 3 | |

| | | | |
|---|---|---|---|
| Psoriasis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 2 | 12 | |
| Purpura | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pyoderma gangrenosum | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Rash | | | |
| subjects affected / exposed | 45 / 3076 (1.46%) | 57 / 3071 (1.86%) | |
| occurrences (all) | 51 | 60 | |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Rash follicular | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Rash macular | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Rash papular | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Rash pruritic | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Rash vesicular | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |

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|---|---|---|---|
| Rosacea | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Scab | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sebaceous gland disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sebaceous hyperplasia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Seborrhoeic dermatitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Skin depigmentation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin discolouration | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Skin exfoliation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Skin fissures | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Skin hyperpigmentation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin irritation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Skin lesion | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 9 | 16 | |

| | | | |
|---|---|---|---|
| Skin mass | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Skin reaction | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Skin ulcer | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 15 | 12 | |
| Solar dermatitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Solar lentigo | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Stasis dermatitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Swelling face | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 4 | |
| Toxic skin eruption | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urticaria | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 9 | 10 | |
| Vitiligo | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Yellow nail syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |

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|---|---|---|---|
| subjects affected / exposed | 26 / 3076 (0.85%) | 31 / 3071 (1.01%) | |
| occurrences (all) | 36 | 33 | |
| Acute prerenal failure | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Albuminuria | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bladder discomfort | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Bladder diverticulum | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Bladder hypertrophy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bladder outlet obstruction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bladder prolapse | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Bladder spasm | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Bladder trabeculation | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Calculus bladder | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Calculus urinary | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Chromaturia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 10 | 10 | |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Diabetic nephropathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Dysuria | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 15 | 14 | |
| End stage renal disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eosinophilic cystitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Haematuria | | | |
| subjects affected / exposed | 36 / 3076 (1.17%) | 36 / 3071 (1.17%) | |
| occurrences (all) | 37 | 38 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 5 | 1 | |
| Hypertensive nephropathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypertonic bladder | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 3 | |
| Lower urinary tract symptoms | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Microalbuminuria | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Micturition disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Micturition urgency | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Myoglobinuria | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nephrectasia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 16 / 3071 (0.52%) | |
| occurrences (all) | 14 | 16 | |
| Nephropathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Neurogenic bladder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nocturia | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 8 | 6 | |
| Oliguria | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pollakiuria | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 9 | 7 | |
| Polyuria | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Proteinuria | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 4 | |
| Pyelocaliectasis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Renal artery stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 3 | |
| Renal cyst | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 14 | 17 | |
| Renal colic | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 10 | 7 | |
| Renal failure | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 10 | 4 | |
| Renal disorder | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Renal impairment | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 13 | 13 | |
| Renal injury | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Renal mass | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Renal pain | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Renal tubular dysfunction | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Stress urinary incontinence | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Ureteric stenosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Urethral haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Urethral polyp | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Urinary bladder haemorrhage | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urinary hesitation | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 16 / 3076 (0.52%) | 21 / 3071 (0.68%) | |
| occurrences (all) | 19 | 22 | |
| Urinary incontinence | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 4 | 9 | |
| Urinary tract disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urine abnormality | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Endocrine disorders | | | |
| Autoimmune thyroiditis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Basedow's disease | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Diabetes insipidus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Euthyroid sick syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Goitre | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Haemorrhagic thyroid cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Hyperparathyroidism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Hypogonadism | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hypogonadism male | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 32 / 3071 (1.04%) | |
| occurrences (all) | 14 | 32 | |

| | | | |
|---|---|---|---|
| Myxoedema | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Primary hypogonadism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Primary hypothyroidism | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Thyroid mass | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Musculoskeletal and connective tissue disorders | | | |
| Ankle impingement | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 104 / 3076 (3.38%) | 113 / 3071 (3.68%) | |
| occurrences (all) | 112 | 122 | |
| Arthritis | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 15 | 12 | |
| Arthritis climacteric | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Arthropathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Back pain | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 121 / 3076 (3.93%) | 124 / 3071 (4.04%) | | |
| occurrences (all) | 132 | 138 | | |
| Bone lesion | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 1 | 1 | | |
| Bone pain | | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | | |
| occurrences (all) | 3 | 2 | | |
| Bone swelling | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Bursitis | | | | |
| subjects affected / exposed | 14 / 3076 (0.46%) | 18 / 3071 (0.59%) | | |
| occurrences (all) | 15 | 18 | | |
| Cervical spinal stenosis | | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 2 | 1 | | |
| Chondrocalcinosis | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Chondromalacia | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Clubbing | | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | | |
| occurrences (all) | 1 | 0 | | |
| Coccydynia | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | | |
| occurrences (all) | 0 | 2 | | |
| Costochondritis | | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | | |
| occurrences (all) | 3 | 3 | | |
| Crystal arthropathy | | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | | |
| occurrences (all) | 0 | 1 | | |
| Diastasis recti abdominis | | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Dupuytren's contracture | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Enthesopathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Exostosis | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 7 | 1 | |
| Extremity contracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Facet joint syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fibromyalgia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Flank pain | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 6 | 10 | |
| Finger deformity | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Foot deformity | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 6 | |
| Gouty arthritis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 2 | 8 | |
| Groin pain | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Hip deformity | | | |

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|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hypotonia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 6 | 3 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 16 / 3076 (0.52%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 17 | 12 | |
| Jaw cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Joint crepitation | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Joint contracture | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Joint hyperextension | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Joint effusion | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Joint range of motion decreased | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Joint stiffness | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Joint swelling | | | |

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|---|---|---|---|
| subjects affected / exposed | 15 / 3076 (0.49%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 16 | 14 | |
| Kyphosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Limb discomfort | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Limb mass | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Metatarsalgia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Mobility decreased | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Muscle atrophy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Muscle contracture | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Muscle disorder | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Muscle fatigue | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |
| Muscle haemorrhage | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Muscle spasms | | | |

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|---|---|---|---|
| subjects affected / exposed | 42 / 3076 (1.37%) | 48 / 3071 (1.56%) | |
| occurrences (all) | 45 | 50 | |
| Muscle tightness | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Muscular weakness | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 10 | 4 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 30 / 3076 (0.98%) | 36 / 3071 (1.17%) | |
| occurrences (all) | 31 | 40 | |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 7 | 5 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 62 / 3076 (2.02%) | 63 / 3071 (2.05%) | |
| occurrences (all) | 67 | 67 | |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 3 | 6 | |
| Myalgia | | | |
| subjects affected / exposed | 106 / 3076 (3.45%) | 108 / 3071 (3.52%) | |
| occurrences (all) | 116 | 119 | |
| Myofascial pain syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Myopathy | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Myositis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Neck pain | | | |
| subjects affected / exposed | 18 / 3076 (0.59%) | 30 / 3071 (0.98%) | |
| occurrences (all) | 18 | 30 | |
| Osteitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Osteitis deformans | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 50 / 3076 (1.63%) | 51 / 3071 (1.66%) | |
| occurrences (all) | 56 | 55 | |
| Osteochondrosis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Osteomalacia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Osteopenia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 3 | 7 | |
| Osteonecrosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Osteoporosis postmenopausal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Osteoporosis | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 6 | 9 | |
| Pain in extremity | | | |
| subjects affected / exposed | 94 / 3076 (3.06%) | 108 / 3071 (3.52%) | |
| occurrences (all) | 105 | 124 | |
| Pain in jaw | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 6 | 1 | |
| Patellofemoral pain syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pathological fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Periarthritis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 4 | 8 | |
| Peripheral arthritis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Plantar fasciitis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 4 | 5 | |
| Polyarthritis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 6 | 7 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 23 / 3076 (0.75%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 25 | 15 | |
| Sacroiliitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Scleroderma | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Scoliosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Senile ankylosing vertebral hyperostosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sjogren's syndrome | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Somatic dysfunction | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Spinal column stenosis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 4 | 7 | |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 12 | 13 | |
| Spinal pain | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 6 | 2 | |
| Spondylitis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Spondylolysis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Synovial cyst | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 6 | 4 | |
| Synovitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |

| | | | |
|---|---|---|---|
| Systemic lupus erythematosus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tendon disorder | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Tendonitis | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 18 / 3071 (0.59%) | |
| occurrences (all) | 15 | 20 | |
| Tenosynovitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Tenosynovitis stenosans | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 0 | 5 | |
| Torticollis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Trigger finger | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 5 | 9 | |
| Vertebral foraminal stenosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Infections and infestations | | | |
| Abdominal infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abscess | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Abscess bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Abscess limb | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Abscess oral | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Acarodermatitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Acute hepatitis B | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Acute sinusitis | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 10 | 19 | |
| Amoebiasis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Anal abscess | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bacteraemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Bacterial vaginosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bacterial infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Balanoposthitis infective | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Beta haemolytic streptococcal infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Body tinea | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Borrelia infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bronchitis | | | |
| subjects affected / exposed | 69 / 3076 (2.24%) | 60 / 3071 (1.95%) | |
| occurrences (all) | 81 | 77 | |
| Bronchitis bacterial | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Bronchitis pneumococcal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Burn infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Campylobacter infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Candida infection | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 5 | 4 | |
| Carbuncle | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |

| | | | |
|---|---|---|---|
| Catheter site infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Cellulitis | | | |
| subjects affected / exposed | 27 / 3076 (0.88%) | 24 / 3071 (0.78%) | |
| occurrences (all) | 29 | 27 | |
| Chorioretinitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Conjunctivitis | | | |
| subjects affected / exposed | 13 / 3076 (0.42%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 15 | 6 | |
| Conjunctivitis bacterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Corona virus infection | | | |
| subjects affected / exposed | 84 / 3076 (2.73%) | 102 / 3071 (3.32%) | |
| occurrences (all) | 84 | 102 | |
| Cystitis | | | |
| subjects affected / exposed | 16 / 3076 (0.52%) | 21 / 3071 (0.68%) | |
| occurrences (all) | 27 | 33 | |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Dacryocystitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Dengue fever | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 4 | |
| Dermatophytosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Dermatophytosis of nail | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Device related infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Diverticulitis | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 12 | 16 | |
| Ear infection | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 12 | 9 | |
| Ear infection bacterial | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Enterococcal infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Epididymitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 5 | |
| Erysipelas | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 7 | 3 | |
| Escherichia infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Eye infection | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 4 | 7 | |
| Eyelid infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Folliculitis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 5 | 1 | |
| Fungal infection | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Fungal skin infection | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 4 | 5 | |
| Furuncle | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 5 | 7 | |
| Gangrene | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastric infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Gastric ulcer helicobacter | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastritis viral | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 31 / 3076 (1.01%) | 29 / 3071 (0.94%) | |
| occurrences (all) | 32 | 30 | |
| Gastroenteritis bacterial | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 2 | |

| | | | |
|---|---|---|---|
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 13 / 3071 (0.42%) | |
| occurrences (all) | 11 | 14 | |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Gastrointestinal viral infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Genital abscess | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Genital herpes | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Giardiasis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Gingival abscess | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gingivitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 6 | |
| Groin abscess | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Haemophilus infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Helicobacter gastritis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |

| | | | |
|---|---|---|---|
| Helicobacter infection | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Hepatitis C | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Herpes virus infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 19 / 3076 (0.62%) | 28 / 3071 (0.91%) | |
| occurrences (all) | 19 | 28 | |
| Hordeolum | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Human ehrlichiosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Incision site infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Infected bite | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Infected bunion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Infected dermal cyst | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Infected skin ulcer | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 2 | 4 | |

| | | | |
|---|---|---|---|
| Infectious mononucleosis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Infection parasitic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Influenza | | | |
| subjects affected / exposed | 67 / 3076 (2.18%) | 72 / 3071 (2.34%) | |
| occurrences (all) | 70 | 76 | |
| Kidney infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Labyrinthitis | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 7 | 7 | |
| Laryngitis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Localised infection | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 7 | 10 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 36 / 3076 (1.17%) | 45 / 3071 (1.47%) | |
| occurrences (all) | 55 | 53 | |
| Lung abscess | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lung infection | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Lyme disease | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |

| | | | |
|---|---|---|---|
| Mastitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Mastoiditis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Myringitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Nail bed infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 103 / 3076 (3.35%) | 124 / 3071 (4.04%) | |
| occurrences (all) | 134 | 168 | |
| Oesophageal candidiasis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Onychomycosis | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 7 | 5 | |
| Ophthalmic herpes simplex | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Oral candidiasis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 6 | |
| Oral fungal infection | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 6 | |
| Oral herpes | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Oral infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

| | | | |
|---|---|---|---|
| Orchitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 4 | 1 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 0 | 5 | |
| Otitis externa | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 9 | 3 | |
| Otitis media | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 4 | 7 | |
| Otitis media acute | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Otitis media chronic | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Paronychia | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 2 | 3 | |
| Parotitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Periodontitis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pharyngitis | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 16 / 3071 (0.52%) | |
| occurrences (all) | 10 | 18 | |

| | | | |
|---|---|---|---|
| Pharyngitis bacterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 0 | 5 | |
| Pilonidal cyst | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 3 | |
| Pneumonia | | | |
| subjects affected / exposed | 42 / 3076 (1.37%) | 46 / 3071 (1.50%) | |
| occurrences (all) | 44 | 51 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pneumonia mycoplasmal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pneumonia pneumococcal | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Post procedural infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 0 | 3 | |
| Post viral fatigue syndrome | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 3 | 4 | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |

| | | | |
|---|---|---|---|
| Pulpitis dental | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Puncture site infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 5 | 2 | |
| Pyelonephritis chronic | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Pyuria | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rectal abscess | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 32 / 3076 (1.04%) | 32 / 3071 (1.04%) | |
| occurrences (all) | 37 | 33 | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 19 / 3071 (0.62%) | |
| occurrences (all) | 17 | 23 | |
| Rhinitis | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 5 | 8 | |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Root canal infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sepsis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 1 | 5 | |
| Severe acute respiratory syndrome | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sexually transmitted disease | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sialoadenitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Sinusitis bacterial | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 3 | |
| Sinusitis | | | |
| subjects affected / exposed | 35 / 3076 (1.14%) | 40 / 3071 (1.30%) | |
| occurrences (all) | 50 | 51 | |
| Skin candida | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 3 | 5 | |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Staphylococcal infection | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 3 | 2 | |

| | | | |
|---|---|---|---|
| Streptococcal infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 2 | 2 | |
| Syphilis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 2 | |
| Tinea capitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tinea cruris | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Tinea infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tinea pedis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Tinea versicolour | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Tonsillitis | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 9 | 7 | |
| Tooth abscess | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 18 / 3071 (0.59%) | |
| occurrences (all) | 11 | 18 | |
| Tooth infection | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 13 / 3071 (0.42%) | |
| occurrences (all) | 13 | 14 | |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Tracheobronchitis | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 5 / 3071 (0.16%) | |
| occurrences (all) | 6 | 5 | |
| Tuberculosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 69 / 3076 (2.24%) | 81 / 3071 (2.64%) | |
| occurrences (all) | 83 | 92 | |
| Urethritis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 88 / 3076 (2.86%) | 100 / 3071 (3.26%) | |
| occurrences (all) | 112 | 135 | |
| Urinary tract infection enterococcal | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vaginal infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 3 | 1 | |
| Varicella | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Varicella zoster virus infection | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Viral infection | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 25 / 3071 (0.81%) | |
| occurrences (all) | 16 | 28 | |
| Vestibular neuronitis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |

| | | | |
|---|---|---|---|
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Viral rhinitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Viral sinusitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 9 / 3076 (0.29%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 11 | 6 | |
| Vulvitis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Vulvovaginitis | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Wound infection | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 6 | 10 | |
| Metabolism and nutrition disorders | | | |
| Abnormal loss of weight | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 0 | 2 | |
| Cachexia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Decreased appetite | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 11 / 3076 (0.36%) | 20 / 3071 (0.65%) | |
| occurrences (all) | 12 | 20 | |
| Dehydration | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 12 | 11 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 82 / 3076 (2.67%) | 63 / 3071 (2.05%) | |
| occurrences (all) | 85 | 65 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 6 | 16 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Diabetic metabolic decompensation | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 5 | 3 | |
| Dyslipidaemia | | | |
| subjects affected / exposed | 12 / 3076 (0.39%) | 10 / 3071 (0.33%) | |
| occurrences (all) | 12 | 11 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fluid overload | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 1 | 3 | |
| Fluid retention | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 2 | 1 | |
| Folate deficiency | | | |
| subjects affected / exposed | 8 / 3076 (0.26%) | 12 / 3071 (0.39%) | |
| occurrences (all) | 8 | 12 | |
| Food aversion | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Food intolerance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Fructose intolerance | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Glucose tolerance impaired | | | |
| subjects affected / exposed | 24 / 3076 (0.78%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 24 | 15 | |
| Gout | | | |
| subjects affected / exposed | 33 / 3076 (1.07%) | 35 / 3071 (1.14%) | |
| occurrences (all) | 38 | 46 | |
| Haemochromatosis | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 16 / 3076 (0.52%) | 9 / 3071 (0.29%) | |
| occurrences (all) | 16 | 11 | |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 6 | 3 | |
| Hyperinsulinaemic hypoglycaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 15 / 3076 (0.49%) | 11 / 3071 (0.36%) | |
| occurrences (all) | 15 | 11 | |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 0 | 4 | |
| Hypernatraemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Hypertriglyceridaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 10 / 3076 (0.33%) | 15 / 3071 (0.49%) | |
| occurrences (all) | 10 | 15 | |
| Hyperuricaemia | | | |
| subjects affected / exposed | 13 / 3076 (0.42%) | 14 / 3071 (0.46%) | |
| occurrences (all) | 14 | 14 | |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 6 / 3076 (0.20%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 7 | 2 | |
| Hypocholesterolaemia | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 17 / 3076 (0.55%) | 17 / 3071 (0.55%) | |
| occurrences (all) | 20 | 20 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 24 / 3076 (0.78%) | 23 / 3071 (0.75%) | |
| occurrences (all) | 28 | 24 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 11 | 8 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 11 / 3076 (0.36%) | 4 / 3071 (0.13%) | |
| occurrences (all) | 11 | 4 | |
| Hypophosphataemia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 4 | 3 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Impaired fasting glucose | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 3076 (0.10%) | 3 / 3071 (0.10%) | |
| occurrences (all) | 3 | 3 | |
| Increased appetite | | | |
| subjects affected / exposed | 2 / 3076 (0.07%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Insulin resistance | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 1 | 1 | |
| Iron deficiency | | | |
| subjects affected / exposed | 10 / 3076 (0.33%) | 8 / 3071 (0.26%) | |
| occurrences (all) | 10 | 8 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lactic acidosis | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 1 | 2 | |
| Malnutrition | | | |
| subjects affected / exposed | 4 / 3076 (0.13%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 2 / 3071 (0.07%) | |
| occurrences (all) | 4 | 2 | |
| Obesity | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 7 / 3071 (0.23%) | |
| occurrences (all) | 5 | 7 | |
| Overweight | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Polydipsia | | | |
| subjects affected / exposed | 3 / 3076 (0.10%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Type 1 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 3076 (0.00%) | 1 / 3071 (0.03%) | |
| occurrences (all) | 0 | 1 | |
| Type 2 diabetes mellitus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 32 / 3076 (1.04%) | 40 / 3071 (1.30%) | |
| occurrences (all) | 32 | 40 | |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 5 / 3076 (0.16%) | 6 / 3071 (0.20%) | |
| occurrences (all) | 5 | 6 | |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 7 / 3076 (0.23%) | 22 / 3071 (0.72%) | |
| occurrences (all) | 7 | 22 | |
| Vitamin K deficiency | | | |
| subjects affected / exposed | 1 / 3076 (0.03%) | 0 / 3071 (0.00%) | |
| occurrences (all) | 1 | 0 | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 07 September 2017 | The original protocol, dated 18 August 2015, was implemented globally. Subsequently, this global protocol was amended 4 times.<br>Protocol Version 2 dated 07 September 2017: In the original protocol DAL-301, women of childbearing potential who were not simultaneously using two effective contraceptive methods, one of which being a barrier method, were excluded from participating, as noted in the minutes from the FDA End-of-Phase 2 meeting on June 16, 2015 and in agency email communication on July 22, 2015, pending the results from an additional hamster embryo-fetal development (EFD) study. On the basis of the completion and results of the additional requested testing in hamsters, as well as the prior testing that evaluated the embryo-fetal effects of dalcetrapib in rats and rabbits, the protocol was amended to allow women of childbearing potential to be included in the study if using only one (rather than two) forms of contraception.<br>Protocol Version 2 was implemented globally with the following exceptions. Canada did not accept the change of allowing women of childbearing potential to enter the study using one instead of two forms of contraception. Belgium and Germany requested the addition of the word "highly" to the description of the requirement for at least one effective method of contraception to be used and required a separate version of the protocol as a result of that request. |
| 23 February 2018 | The original DAL-301 sample size and anticipated treatment effect was based on the pharmacogenomics evaluation in the dal-OUTCOMES study that demonstrated a 39% reduction in CV risk in subjects with the AA genotype at variant rs1967309 in the ADCY9 gene with dalcetrapib compared to placebo. The initial design of DAL-301 proposed that a 25% reduction was appropriate as a conservative estimate for this prospective study. The study protocol was subsequently amended to change the target number of patients with a primary endpoint from 434 to 582, so that the study would have 85% power (two-sided alpha of 0.05) to detect a relative risk<br>reduction of 22%. The minimally detectable risk reduction under this plan is 15%. A 15% relative risk reduction has been used in the design of other cardiovascular endpoint studies, including other CETP trials, since this level of risk reduction would provide clinically significant medical benefit on top of statin therapy. |
| 04 August 2020 | The public health and safety concerns resulting from the COVID-19 pandemic resulted in challenges adhering to DAL-301 protocol-mandated study visits and corresponding study drug dispensation. Modifications to the protocol were made to help protect patient safety, while maintaining compliance with Good Clinical Practice Guidelines and minimizing risks to study integrity. These included allowing in-person patient visits to be replaced by phone visits or virtual visits, and for patient communication to occur through email and text message. Sponsor approval was required for patients taking study medication without blood pressure, pulse, or weight<br>assessments for more than one year. Study medication was permitted to be dispensed within a study visit window or in advance through a secure delivery method. All study medication was appropriately handled and tracked to ensure compliance with stability parameters. Patients were provided directions to save their unused study medication materials (used and unused drug supply containers) to return at their next on-site visit. Study medication was also allowed to be returned by the patient to the site through a secure delivery method. Additionally, monitors were allowed to perform monitoring visits virtually when access to sites in-person was not available. |

| | |
|---|---|
| 11 February 2021 | Additional modifications to the protocol were made in response to the COVID-19 pandemic. The physical exam and vital signs (blood pressure, pulse, and weight) at the EOS Visit were made optional, performed whenever possible. This was done to ensure the safety of patients and study staff and in light of significant safety data already available on dalcetrapib. The physical exam and vital signs were also allowed to be performed outside of the clinical site (i.e., a remote location, the patient's home, etc.) due to many sites that were closed or had limited access during the<br>pandemic. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported

## Online references

http://www.ncbi.nlm.nih.gov/pubmed/32087417