# Clinical trial results:
# A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome

## Summary

| | |
|---|---|
| EudraCT number | 2017-000996-98 |
| Trial protocol | GB LV SE PT FI BE LT DK EE DE AT CZ NO HU FR NL ES SK BG GR HR IT RO |
| Global end of trial date | 17 November 2023 |

### Results information

| | |
|---|---|
| Result version number | v2 (current) |
| This version publication date | 13 February 2025 |
| First version publication date | 20 October 2024 |
| Version creation reason | • Correction of full data set<br>Minor updates have been made to align the results posting with the study's clinicaltrials.gov results record. |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | CSL112_3001 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03473223 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | CSL Behring LLC |
| Sponsor organisation address | 1020 First Avenue, King of Prussia, PA, United States, 19406-0901 |
| Public contact | Trial Registration Coordinator, CSL Behring LLC, +1 610-878-4000, clinicaltrials@cslbehring.com |
| Scientific contact | Trial Registration Coordinator, CSL Behring LLC, +1 610-878-4000, clinicaltrials@cslbehring.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 | 24 January 2024 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 17 November 2023 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the efficacy of CSL112 in reducing the risk of Major adverse cardiovascular event (MACE) (cardiovascular [CV] death, myocardial infarction [MI], or stroke) from the time of randomisation through 90 days in subjects with acute coronary syndrome (ACS) (diagnosed with ST-segment elevation myocardial infarction [STEMI] or Non-ST-segment elevation myocardial infarction [NSTEMI]).

Protection of trial subjects:

This study was carried out in accordance with the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, the ethical principles that have their origin in the Declaration of Helsinki, all applicable national and local regulations, and standard operating procedures for clinical research and development at CSL Behring (CSL). The study protocol and all amendments were approved by the Independent Ethics Committee (IEC) of the participating center. Before any protocol-specific procedures were carried out, participants were informed, in an understandable form, about the nature, scope, and possible consequences of the study. Participant informed consent was obtained and documented according to the provisions of ICH GCP and applicable regulatory requirements. Written informed consent was provided by each participant before any protocol-specific procedures were carried out.

| | |
|---|---|
| Background therapy: - | |
| Evidence for comparator: - | |
| Actual start date of recruitment | 21 March 2018 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy |
| Long term follow-up duration | 1 Years |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Argentina: 869 |
| Country: Number of subjects enrolled | Chile: 53 |
| Country: Number of subjects enrolled | Colombia: 137 |
| Country: Number of subjects enrolled | Malaysia: 278 |
| Country: Number of subjects enrolled | New Zealand: 101 |
| Country: Number of subjects enrolled | Peru: 14 |
| Country: Number of subjects enrolled | Singapore: 39 |
| Country: Number of subjects enrolled | United Kingdom: 99 |
| Country: Number of subjects enrolled | United States: 1845 |

| | |
|---|---|
| Country: Number of subjects enrolled | Austria: 122 |
| Country: Number of subjects enrolled | Belgium: 178 |
| Country: Number of subjects enrolled | Bulgaria: 553 |
| Country: Number of subjects enrolled | Croatia: 40 |
| Country: Number of subjects enrolled | Czechia: 106 |
| Country: Number of subjects enrolled | Denmark: 177 |
| Country: Number of subjects enrolled | Estonia: 149 |
| Country: Number of subjects enrolled | Finland: 24 |
| Country: Number of subjects enrolled | France: 193 |
| Country: Number of subjects enrolled | Germany: 337 |
| Country: Number of subjects enrolled | Greece: 152 |
| Country: Number of subjects enrolled | Hungary: 904 |
| Country: Number of subjects enrolled | Italy: 181 |
| Country: Number of subjects enrolled | Latvia: 69 |
| Country: Number of subjects enrolled | Lithuania: 210 |
| Country: Number of subjects enrolled | Netherlands: 1486 |
| Country: Number of subjects enrolled | Norway: 36 |
| Country: Number of subjects enrolled | Poland: 1006 |
| Country: Number of subjects enrolled | Portugal: 151 |
| Country: Number of subjects enrolled | Romania: 764 |
| Country: Number of subjects enrolled | Slovakia: 16 |
| Country: Number of subjects enrolled | Spain: 167 |
| Country: Number of subjects enrolled | Sweden: 26 |
| Country: Number of subjects enrolled | Türkiye: 450 |
| Country: Number of subjects enrolled | Switzerland: 172 |
| Country: Number of subjects enrolled | Ukraine: 734 |
| Country: Number of subjects enrolled | Hong Kong: 35 |
| Country: Number of subjects enrolled | Taiwan: 194 |
| Country: Number of subjects enrolled | Australia: 329 |
| Country: Number of subjects enrolled | Brazil: 1553 |
| Country: Number of subjects enrolled | Canada: 508 |
| Country: Number of subjects enrolled | Georgia: 178 |
| Country: Number of subjects enrolled | Israel: 1015 |
| Country: Number of subjects enrolled | Japan: 322 |
| Country: Number of subjects enrolled | Korea, Republic of: 194 |
| Country: Number of subjects enrolled | Mexico: 283 |
| Country: Number of subjects enrolled | Russian Federation: 878 |
| Country: Number of subjects enrolled | Serbia: 511 |
| Country: Number of subjects enrolled | South Africa: 100 |
| Country: Number of subjects enrolled | Thailand: 281 |
| Worldwide total number of subjects | 18219 |
| EEA total number of subjects | 7047 |

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 | 0 |

| | |
|---|---|
| months) | |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 7460 |
| From 65 to 84 years | 10435 |
| 85 years and over | 324 |

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 897 centers across 5 regions (North America, Latin America, Western Europe, Central and Eastern Europe, and Asia Pacific).

### Pre-assignment

Screening details:

A total of 18,848 participants were screened, with 622 identified as screen failures. Of the screened participants, 18,226 were randomized in 1:1 ratio to receive study interventions (CSL112 or Placebo), and 7 of these randomized participants were excluded from analysis per sponsor decision. Intent-to-treat population used for disposition.

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | CSL112 |

Arm description:

Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Apolipoprotein A-I [human] (apoA-I) |
| Investigational medicinal product code | CSL112 |
| Other name | CSL112 |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Apolipoprotein A-I [human] (apoA-I) purified from human plasma for intravenous administration.

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

Arm description:

Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks.

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | Placebo |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

25% albumin solution diluted to 4.4% was administered IV at the same volume and duration as that of CSL112.

| **Number of subjects in period 1** | CSL112 | Placebo |
|---|---|---|
| Started | 9112 | 9107 |
| Safety Analysis Set (SAS) | 9010 | 9027 |
| Completed | 9002 | 9020 |
| Not completed | 110 | 87 |
| Indirect contact | 32 | 29 |
| Other-unspecified | 30 | 15 |
| Withdrawal by Subject | 47 | 42 |
| Lost to follow-up | 1 | 1 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | CSL112 |
| Reporting group description: | |
| Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks. | |

| Reporting group title | Placebo |
|---|---|
| Reporting group description: | |
| Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks. | |

| Reporting group values | CSL112 | Placebo | Total |
|---|---|---|---|
| Number of subjects | 9112 | 9107 | 18219 |
| Age categorical | | | |
| Units: Subjects | | | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 65.6 | 65.4 | |
| standard deviation | ± 10.09 | ± 10.21 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 2326 | 2386 | 4712 |
| Male | 6786 | 6721 | 13507 |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 1566 | 1596 | 3162 |
| Not Hispanic or Latino | 7410 | 7383 | 14793 |
| Unknown or Not Reported | 136 | 128 | 264 |
| Race | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 51 | 36 | 87 |
| Asian | 743 | 781 | 1524 |
| Native Hawaiian or Other Pacific Islander | 8 | 10 | 18 |
| Black or African American | 181 | 181 | 362 |
| White | 7769 | 7698 | 15467 |
| Multiracial or other | 314 | 356 | 670 |
| Unknown or Not Reported | 46 | 45 | 91 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | CSL112 |

Reporting group description:

Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks.

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

Reporting group description:

Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks.

### Primary: Number of Participants With First Occurrence of Any Component of Composite MACE (CV Death, MI, or Stroke)

| | |
|---|---|
| End point title | Number of Participants With First Occurrence of Any Component of Composite MACE (CV Death, MI, or Stroke) |

End point description:

MACE (Major adverse cardiovascular event[s])(CV [cardiovascular] death, MI [Myocardial Infarction], or stroke). Analysis was performed on the intent-to-treat (ITT) analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 90 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | 439 | 472 | | |

### Statistical analyses

| Statistical analysis title | CSL112 versus Placebo |
|---|---|
| Comparison groups | CSL112 v Placebo |
| Number of subjects included in analysis | 18219 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.121 [1] |
| Method | Cox proportional hazards regression |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.925 |

| Confidence interval | |
|---|---|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8126 |
| upper limit | 1.0538 |

Notes:

[1] - 1-sided p-value.

## Secondary: Total Number of Hospitalizations for Coronary, Cerebral, or Peripheral Ischemia

| End point title | Total Number of Hospitalizations for Coronary, Cerebral, or Peripheral Ischemia |
|---|---|

End point description:

The total number of hospitalizations and individual hospitalizations due to coronary, cerebral, and peripheral ischemia were reported. Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 90 days

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: hospitalizations | | | | |
| number (not applicable) | | | | |
| Total hospitalizations | 433 | 442 | | |
| Coronary ischemia | 367 | 376 | | |
| Cerebral ischemia | 39 | 36 | | |
| Peripheral ischemia | 27 | 30 | | |

### Statistical analyses

| **Statistical analysis title** | CSL112 versus Placebo |
|---|---|
| Comparison groups | CSL112 v Placebo |
| Number of subjects included in analysis | 18219 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.341 [2] |
| Method | Negative binomial regression model |
| Parameter estimate | Rate ratio |
| Point estimate | 0.971 |

| | |
|---|---|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8442 |
| upper limit | 1.1171 |

Notes:

[2] - 1-sided p-value.

## Secondary: Number of Participants With First Occurrence of CV Death, MI, or Stroke

| | |
|---|---|
| End point title | Number of Participants With First Occurrence of CV Death, MI, or Stroke |

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 180 days

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | 622 | 683 | | |

### Statistical analyses

| **Statistical analysis title** | CSL112 versus Placebo |
|---|---|
| Comparison groups | CSL112 v Placebo |
| Number of subjects included in analysis | 18219 |
| Analysis specification | Pre-specified |
| Analysis type | superiority[3] |
| P-value | = 0.038 |
| Method | Cox proportional hazards regression |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.907 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8132 |
| upper limit | 1.0106 |

Notes:

[3] - 1-sided p-value.

## Secondary: Number of Participants With First Occurrence of CV Death, MI, or Stroke

| | |
|---|---|
| End point title | Number of Participants With First Occurrence of CV Death, MI, |

| | |
|---|---|
| | or Stroke |

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 365 days

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | 885 | 944 | | |

**Statistical analyses**

| **Statistical analysis title** | CSL112 versus Placebo |
|---|---|
| Comparison groups | CSL112 v Placebo |
| Number of subjects included in analysis | 18219 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.069 [4] |
| Method | Cox proportional hazards regression |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.933 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8511 |
| upper limit | 1.0224 |

Notes:

[4] - 1-sided p-value.

**Secondary: Number of Participants With Occurrence of CV Death**

| | |
|---|---|
| End point title | Number of Participants With Occurrence of CV Death |

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 90 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | 107 | 128 | | |

**Statistical analyses**

| Statistical analysis title | CSL112 versus Placebo |
|---|---|
| Comparison groups | CSL112 v Placebo |
| Number of subjects included in analysis | 18219 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.074 [5] |
| Method | Cox proportional hazards regression |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.827 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6399 |
| upper limit | 1.0695 |

Notes:

[5] - 1-sided p-value.

**Secondary: Number of Participants With First Occurrence of MI**

| End point title | Number of Participants With First Occurrence of MI |
|---|---|

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 90 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | 312 | 342 | | |

**Statistical analyses**

| **Statistical analysis title** | CSL112 versus Placebo |
|---|---|
| Comparison groups | CSL112 v Placebo |
| Number of subjects included in analysis | 18219 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.113 [6] |
| Method | Cox proportional hazards regression |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.909 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7801 |
| upper limit | 1.0603 |

Notes:

[6] - 1-sided p-value.

| **Secondary: Number of Participants With First Occurrence of Stroke** | |
|---|---|
| End point title | Number of Participants With First Occurrence of Stroke |

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 90 days

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | 57 | 49 | | |

**Statistical analyses**

| **Statistical analysis title** | CSL112 versus Placebo |
|---|---|
| Comparison groups | CSL112 v Placebo |
| Number of subjects included in analysis | 18219 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.767 [7] |
| Method | Cox proportional hazards regression |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.153 |

| Confidence interval | |
|---|---|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7867 |
| upper limit | 1.6886 |

Notes:

[7] - 1-sided p-value.

## Secondary: Number of Participants With First Occurrence of CV Death, Type 1 MI or Stroke

| End point title | Number of Participants With First Occurrence of CV Death, Type 1 MI or Stroke |
|---|---|

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 90, 180 and 365 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | | | | |
| Through Day 90 | 272 | 308 | | |
| Through Day 180 | 400 | 444 | | |
| Through Day 365 | 594 | 639 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Occurrence of All-cause Death

| End point title | Number of Participants With Occurrence of All-cause Death |
|---|---|

End point description:

Analysis was performed on the ITT analysis set. The ITT analysis set comprised all randomized participants with the exception of 7 participants enrolled at site(s) excluded from analysis per sponsor decision. The ITT analysis set utilized the treatment to which the participant was randomized regardless of the treatment actually received.

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

End point timeframe:

From the time of randomization through 365 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9112 | 9107 | | |
| Units: participants | 341 | 345 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With Adverse Events

| End point title | Number of Participants With Adverse Events |
|---|---|

End point description:

An AE was defined as any unfavorable and unintended sign (including an abnormal, clinically significant laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product. Analysis was performed on the Safety analysis set (SAS). The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

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

End point timeframe:

From the start of treatment through 90 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9010 | 9027 | | |
| Units: participants | 3938 | 3927 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With Adverse Events

| End point title | Percentage of Participants With Adverse Events |
|---|---|

End point description:

An AE was defined as any unfavorable and unintended sign (including an abnormal, clinically significant laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not considered related to the medicinal (investigational) product. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

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

End point timeframe:

From the start of treatment through 90 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9010 | 9027 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 43.7 | 43.5 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants With Treatment-related Adverse Events

| End point title | Number of Participants With Treatment-related Adverse Events |
|---|---|

End point description:

Treatment-related AEs were AEs considered by the Investigator to have a causal relationship to the investigational product. Analysis was performed on the SAS.The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

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

End point timeframe:

From the start of treatment through 379 days (Day 365 + 14 days of follow up)

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9010 | 9027 | | |
| Units: participants | 350 | 304 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Treatment-related Adverse Events

| End point title | Percentage of Participants With Treatment-related Adverse Events |
|---|---|

End point description:

Treatment-related AEs were AEs considered by the Investigator to have a causal relationship to the investigational product. As per the study statistical analysis plan (SAP), descriptive percentages were displayed to one decimal place, hence the percentage values were rounded off and presented. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

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

End point timeframe:

From the start of treatment through 379 days (Day 365 + 14 days of follow up)

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9010 | 9027 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 3.9 | 3.4 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants With Serious Adverse Events (SAEs)

| End point title | Number of Participants With Serious Adverse Events (SAEs) |
|---|---|

End point description:

SAE was defined as any untoward medical occurrence that at any dose: results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect or is a medically significant event. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

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

End point timeframe:

From the start of treatment through 379 days (Day 365 + 14 days of follow up)

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9010 | 9027 | | |
| Units: participants | 1514 | 1557 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With SAEs

| End point title | Percentage of Participants With SAEs |
|---|---|

End point description:

SAE was defined as any untoward medical occurrence that at any dose: results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly or birth defect or is a medically significant event. As per the SAP, descriptive percentages were displayed to one decimal place, hence the percentage values were rounded off and presented. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received.

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

End point timeframe:

From the start of treatment through 379 days (Day 365 + 14 days of follow up)

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9010 | 9027 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 16.8 | 17.2 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments

| End point title | Number of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments |
|---|---|

End point description:

Clinical laboratory assessments included assessment of Hematology (hemoglobin, hematocrit, leukocytes and platelets) and Biochemistry (alkaline phosphatase [ALP], alanine aminotransferase [ALT], aspartate aminotransferase [AST], bilirubin and estimated glomerular filtration rate [eGFR]). Number of participants with shift from Baseline value to worst post-treatment value (low, normal, or high) was reported. Worst criterion for parameters is as follows: hematocrit - low, hemoglobin - low, leukocytes - high, platelets - low,ALT - high, ALP - high, AST - high, bilirubin - high, direct bilirubin - high, indirect bilirubin - high, eGFR -severe impairment. SAS comprised all participants in ITT Analysis set who received any amount of investigational product, and were analyzed based on actual treatment received. Here, number of participants analysed (N) = all participants who were evaluated for this endpoint."n" = participants who were evaluated for this endpoint for the specified category.

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

End point timeframe:

Baseline and 29 days

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8372 | 8392 | | |
| Units: participants | | | | |
| Hematocrit - High to Low (n=6848, 6810) | 0 | 1 | | |
| Hematocrit - Normal to Low (n=6848, 6810) | 365 | 393 | | |
| Hemoglobin - High to Low (n=7235,7185) | 0 | 1 | | |
| Hemoglobin - Normal to Low (n=7235,7185) | 457 | 447 | | |
| Leukocytes - Normal to High (n=7229,7184) | 267 | 271 | | |

| | | | | |
|---|---|---|---|---|
| Leukocytes - Low to High (n=7229,7184) | 2 | 1 | | |
| Platelets - High to Low (n=7138,7064) | 0 | 0 | | |
| Platelets - Normal to Low (n=7138,7064) | 92 | 114 | | |
| ALT - Normal to High (n=7904,7949) | 658 | 612 | | |
| ALT - Low to High (n=7904,7949) | 0 | 0 | | |
| ALP - Normal to High (n=8341,8366) | 307 | 350 | | |
| ALP - Low to High (n=8341,8366) | 1 | 0 | | |
| AST - Normal to High (n=7910,7911) | 239 | 253 | | |
| AST - Low to High (n=7910,7911) | 2 | 0 | | |
| Bilirubin - Normal to High (n=8281,8284) | 73 | 112 | | |
| Bilirubin - Low to High (n=8281,8284) | 0 | 1 | | |
| Direct Bilirubin - Normal to High (n=7273,7317) | 18 | 21 | | |
| Direct Bilirubin - Low to High (n=7273,7317) | 0 | 0 | | |
| Indirect Bilirubin - Normal to High (n=7269,7309) | 31 | 42 | | |
| Indirect Bilirubin - Low to High (n=7269,7309) | 0 | 0 | | |
| eGFR - Normal to Severe (n=8372,8392) | 1 | 2 | | |
| eGFR - Mild to Severe (n=8372,8392) | 15 | 9 | | |
| eGFR - Moderate to Severe (n=8372,8392) | 91 | 99 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments

| End point title | Percentage of Participants With a Shift From Baseline to Worst Post-treatment Value in Clinical Laboratory Assessments |
|---|---|

End point description:

Clinical laboratory assessments included assessment of Hematology (hemoglobin, hematocrit, leukocytes and platelets) and Biochemistry (ALP, ALT, AST, bilirubin and eGFR). Percentage of participants with a shift from the Baseline value to the worst post-treatment value (low, normal, or high) was reported. The worst criterion for the parameters is as follows: hematocrit - low, hemoglobin - low, leukocytes - high, platelets - low, ALT - high, ALP - high, AST - high, bilirubin - high, direct bilirubin - high, indirect bilirubin - high, eGFR - severe impairment. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this endpoint for the specified category.

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

End point timeframe:

Baseline and 29 days

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8372 | 8392 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Hematocrit - High to Low (n=6848, 6810) | 0.0 | 0.0 | | |
| Hematocrit - Normal to Low (n=6848, 6810) | 5.3 | 5.8 | | |
| Hemoglobin - High to Low (n=7235,7185) | 0.0 | 0.0 | | |
| Hemoglobin - Normal to Low (n=7235,7185) | 6.3 | 6.2 | | |
| Leukocytes - Normal to High (n=7229,7184) | 3.7 | 3.8 | | |
| Leukocytes - Low to High (n=7229,7184) | 0.0 | 0.0 | | |
| Platelets - High to Low (n=7138,7064) | 0.0 | 0.0 | | |
| Platelets - Normal to Low (n=7138,7064) | 1.3 | 1.6 | | |
| ALT - Normal to High (n=7904,7949) | 8.3 | 7.7 | | |
| ALT - Low to High (n=7904,7949) | 0.0 | 0.0 | | |
| ALP - Normal to High (n=8341,8366) | 3.7 | 4.2 | | |
| ALP - Low to High (n=8341,8366) | 0.0 | 0.0 | | |
| AST - Normal to High (n=7910,7911) | 3.0 | 3.2 | | |
| AST - Low to High (n=7910,7911) | 0.0 | 0.0 | | |
| Bilirubin - Normal to High (n=8281,8284) | 0.9 | 1.4 | | |
| Bilirubin - Low to High (n=8281,8284) | 0.0 | 0.0 | | |
| Direct Bilirubin - Normal to High (n=7273,7317) | 0.2 | 0.3 | | |
| Direct Bilirubin - Low to High (n=7273,7317) | 0.0 | 0.0 | | |
| Indirect Bilirubin - Normal to High (n=7269,7309) | 0.4 | 0.6 | | |
| Indirect Bilirubin - Low to High (n=7269,7309) | 0.0 | 0.0 | | |
| eGFR - Normal to Severe (n=8372,8392) | 0.0 | 0.0 | | |
| eGFR - Mild to Severe (n=8372,8392) | 0.2 | 0.1 | | |
| eGFR - Moderate to Severe (n=8372,8392) | 1.1 | 1.2 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Hematology Parameters

| End point title | Change From Baseline in Hematology Parameters |
|---|---|

End point description:

Hematology parameters included Basophils, Eosinophils, Leukocytes, Lymphocytes, Monocytes, Neutrophils and Platelets. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this

endpoint for the specified category.

| End point type | Secondary |
|---|---|
| End point timeframe: | |
| From Baseline to Day 29 | |

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7073 | 7021 | | |
| Units: 10^9 cells per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| Basophils (n=7061,7011) | 0.004 (± 0.0455) | 0.005 (± 0.0462) | | |
| Eosinophils (n=7061,7011) | 0.045 (± 0.1766) | 0.047 (± 0.1727) | | |
| Leukocytes (n=7073,7021) | -1.024 (± 2.2905) | -0.969 (± 2.2683) | | |
| Lymphocytes (n=7061,7011) | 0.084 (± 0.5534) | 0.080 (± 0.5409) | | |
| Monocytes (n=7061,7011) | -0.089 (± 0.1886) | -0.087 (± 0.1961) | | |
| Neutrophils (n=7061,7011) | -1.068 (± 2.0892) | -1.011 (± 2.0343) | | |
| Platelets (n=6985,6908) | 0.4 (± 56.09) | -1.4 (± 55.31) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Hematology Parameter: Hematocrit

| End point title | Change From Baseline in Hematology Parameter: Hematocrit |
|---|---|

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

| End point type | Secondary |
|---|---|
| End point timeframe: | |
| From Baseline to Day 29 | |

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6698 | 6651 | | |
| Units: litre per litre (L/L) | | | | |
| arithmetic mean (standard deviation) | -0.003 (± 0.0382) | -0.004 (± 0.0381) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Hematology Parameter: Hemoglobin

| End point title | Change From Baseline in Hematology Parameter: Hemoglobin |
|---|---|

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed included all participants who were evaluated for this endpoint.

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

End point timeframe:

From Baseline to Day 29

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 7074 | 7021 | | |
| Units: grams per litre (g/L) | | | | |
| arithmetic mean (standard deviation) | -1.1 (± 11.96) | -1.3 (± 12.08) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Hepatic Parameters

| End point title | Change From Baseline in Hepatic Parameters |
|---|---|

End point description:

Hepatic parameters included ALT, ALP and AST. Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this endpoint for the specified category.

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

End point timeframe:

From Baseline to Day 29

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8079 | 8072 | | |
| Units: units per litre | | | | |
| arithmetic mean (standard deviation) | | | | |
| ALT (n=7628,7630) | -5.5 (± 25.52) | -6.5 (± 28.91) | | |
| ALP (n=8079,8072) | 3.2 (± 26.13) | 4.5 (± 24.55) | | |
| AST (n=7616,7574) | -21.2 (± 41.90) | -20.7 (± 61.63) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Hepatic Parameter: Bilirubin

| End point title | Change From Baseline in Hepatic Parameter: Bilirubin |
|---|---|

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint and "n" included all participants who were evaluated for this endpoint for the specified category.

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

End point timeframe:

From Baseline to Day 29

| End point values | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8005 | 7983 | | |
| Units: micromol per litre (umol/L) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Bilirubin (n=8005,7983) | -2.6 (± 4.71) | -1.9 (± 5.05) | | |
| Direct Bilirubin (n=6961,6958) | -0.4 (± 1.32) | -0.3 (± 1.75) | | |
| Indirect Bilirubin (n=6957,6950) | -2.0 (± 3.85) | -1.4 (± 3.90) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Renal Parameter: Serum Creatinine

| End point title | Change From Baseline in Renal Parameter: Serum Creatinine |
|---|---|

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

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

End point timeframe:

From Baseline to Day 29

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8114 | 8101 | | |
| Units: umol/L | | | | |
| arithmetic mean (standard deviation) | 2.4 (± 24.39) | 2.1 (± 21.23) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Renal Parameter: eGFR

| End point title | Change From Baseline in Renal Parameter: eGFR |
|---|---|

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

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

End point timeframe:

From Baseline to Day 29

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8112 | 8098 | | |
| Units: millilitre per minute per 1.73 meter^2 | | | | |
| arithmetic mean (standard deviation) | -1.3 (± 11.87) | -1.2 (± 12.15) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Renal Parameter: Blood Urea Nitrogen

| End point title | Change From Baseline in Renal Parameter: Blood Urea Nitrogen |
|---|---|

End point description:

Analysis was performed on the SAS. The SAS comprised all participants in the ITT Analysis set who received any amount of the investigational product, and were analyzed based on the actual treatment received. Here, the number of participants analyzed (N), included all participants who were evaluated for this endpoint.

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

End point timeframe:

From Baseline to Day 29

| **End point values** | CSL112 | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8114 | 8105 | | |
| Units: millimoles per litre | | | | |
| arithmetic mean (standard deviation) | 0.0 (± 2.76) | 0.0 (± 2.67) | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information[1]

Timeframe for reporting adverse events:

All AEs were collected through Day 90 and AEs related to study drug, those leading to its discontinuation, withdrawal of consent, all-cause mortality, Other AEs and all SAEs were collected up to Day 379 (Day 365+ 14 days of follow-up)

Adverse event reporting additional description:

All-cause mortality was monitored/assessed for the ITT population (N = 9112 for CSL112 and N= 9107 for Placebo), but Serious and Other AEs were only monitored/assessed for the SAS population. SAS was the primary population for summarizing and reporting safety data (SAEs and Other AEs).

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 26.1 |

### Reporting groups

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

Reporting group description:

Participants received placebo (25% albumin solution diluted to 4.4%) once weekly via IV infusion for up to 4 weeks.

| | |
|---|---|
| Reporting group title | CSL112 |

Reporting group description:

Participants received 6 grams of CSL112 (apoA-I purified from human plasma) once weekly via IV infusion for up to 4 weeks.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There were no non-serious adverse events above the threshold of 5%.

| Serious adverse events | Placebo | CSL112 | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1557 / 9027 (17.25%) | 1514 / 9010 (16.80%) | |
| number of deaths (all causes) | 355 | 348 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Colon cancer | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Small cell lung cancer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | |
| Gastric cancer | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Prostate cancer | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma gastric | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of colon | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clear cell renal cell carcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to liver | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Small cell lung cancer metastatic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant neoplasm of unknown primary site | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer metastatic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal tract adenoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Benign pancreatic neoplasm | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder papilloma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carcinoid tumour pulmonary | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangiocarcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 9027 (0.04%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon neoplasm | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder adenocarcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder neoplasm | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer stage 0 | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal adenocarcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Glioblastoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma multiforme | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemangioma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| 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 | 4 / 9027 (0.04%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung cancer metastatic | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Lung squamous cell carcinoma stage IV | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant oligodendroglioma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to bone marrow | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastases to lung | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic malignant melanoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic neoplasm | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastatic uterine cancer | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Neuroendocrine tumour | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Hodgkin's lymphoma recurrent | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal carcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pancreatic carcinoma metastatic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pituitary tumour benign | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer metastatic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Renal cancer | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland neoplasm | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Small intestine adenocarcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral cancer metastatic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval cancer | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal adenoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| B-cell lymphoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma stage II | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Borderline mucinous tumour of ovary | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm benign | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Choroid melanoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ciliary body melanoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal adenoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial adenocarcinoma | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial cancer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial cancer stage I | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stromal tumour | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal adenocarcinoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal papilloma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma stage IV | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant urinary tract neoplasm | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic renal cell carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ovarian cancer stage III | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pancreatic carcinoma stage IV | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic neuroendocrine tumour | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary cystadenoma lymphomatosum | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma cell myeloma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer stage II | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic adenoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 renal pelvis and ureter metastatic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma recurrent | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tumour necrosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Hypotension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 15 / 9027 (0.17%) | 17 / 9010 (0.19%) | |
| occurrences causally related to treatment / all | 2 / 15 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 11 / 9010 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 14 / 9027 (0.16%) | 11 / 9010 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 12 / 9027 (0.13%) | 10 / 9010 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 15 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 11 / 9027 (0.12%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Aortic stenosis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral ischaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 9027 (0.06%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic dissection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phlebitis | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiodysplasia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic thrombosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Circulatory collapse | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dialysis hypotension | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granulomatosis with polyangiitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemodynamic instability | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive urgency | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemic shock | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 9027 (0.06%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Iliac artery stenosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoedema | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial rupture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic vascular disorder | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dry gangrene | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leriche syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral vascular disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Raynaud's phenomenon | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Assisted suicide | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| General disorders and administration site conditions | | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 78 / 9027 (0.86%) | 92 / 9010 (1.02%) | |
| occurrences causally related to treatment / all | 1 / 99 | 0 / 97 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 12 / 9010 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 15 / 9027 (0.17%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Vascular stent stenosis | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Gait disturbance | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Medical device site haematoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Drowning | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Impaired healing | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infusion site reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent occlusion | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adverse drug reaction | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthenia | | | |
| subjects affected / exposed | 10 / 9027 (0.11%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug intolerance | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fatigue | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune-mediated polyserositis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Physical deconditioning | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden cardiac death | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sudden death | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Vascular stent thrombosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 2 / 2 | 4 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytokine storm | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic shock | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Loss of personal independence in daily activities | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Victim of abuse | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Physical disability | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Reproductive system and breast disorders** | | | |
| Prostatitis | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular pain | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic haematoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic pain | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Prostatic disorder | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 29 / 9027 (0.32%) | 21 / 9010 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 41 | 0 / 28 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Dyspnoea | | | |
| subjects affected / exposed | 13 / 9027 (0.14%) | 17 / 9010 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 14 | 2 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 12 / 9027 (0.13%) | 14 / 9010 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Respiratory failure | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 10 / 9010 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Epistaxis | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Pleural effusion | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute pulmonary oedema | | | |
| subjects affected / exposed | 11 / 9027 (0.12%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Asthma | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrothorax | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pulmonary congestion | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Asthma-chronic obstructive pulmonary disease overlap syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthmatic crisis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diaphragmatic abnormal relaxation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea at rest | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysema | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiccups | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Idiopathic pulmonary fibrosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Laryngeal oedema | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive airways disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rales | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheal fistula | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alveolar proteinosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiectasis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infiltration | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinal haematoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthopnoea | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleurisy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax spontaneous | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary alveolar haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheomalacia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic wound | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Delirium | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 9027 (0.07%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Panic attack | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholism | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar disorder | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional state | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tobacco withdrawal symptoms | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adjustment disorder with depressed mood | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety disorder | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety disorder due to a general medical condition | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Completed suicide | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Depression | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disorientation | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mixed anxiety and depressive disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device occlusion | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device dislocation | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Cholecystitis | | | |
| subjects affected / exposed | 12 / 9027 (0.13%) | 18 / 9010 (0.20%) | |
| occurrences causally related to treatment / all | 1 / 13 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 17 / 9027 (0.19%) | 11 / 9010 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver injury | | | |
| subjects affected / exposed | 12 / 9027 (0.13%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 4 / 12 | 2 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stone | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis chronic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder rupture | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis acute | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary dyskinesia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis acute | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis obstructive | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug-induced liver injury | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cirrhosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hepatic fibrosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis cholestatic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic failure | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-alcoholic steatohepatitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Troponin increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 2 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ejection fraction decreased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoglobin decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 9027 (0.06%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza A virus test positive | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anticoagulation drug level abnormal | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial test positive | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood magnesium decreased | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerular filtration rate decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory marker increased | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test increased | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Occult blood positive | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SARS-CoV-2 test positive | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiogram peripheral abnormal | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood urine present | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (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 | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gram stain positive | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary arterial pressure increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin T increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | | | |
| Fall | | | |
| subjects affected / exposed | 11 / 9027 (0.12%) | 11 / 9010 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haematoma | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 9 / 9010 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 11 / 9027 (0.12%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hip fracture | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periprocedural myocardial infarction | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular access site haematoma | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac procedure complication | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniofacial fracture | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple injuries | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 9027 (0.04%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pneumothorax | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Vascular access site haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound dehiscence | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic leak | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia postoperative | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chemical burns of eye | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costal cartilage fracture | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eschar | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exposure to SARS-CoV-2 | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Face injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal anastomotic leak | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Overdose | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural myocardial infarction | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative thoracic procedure complication | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative thrombosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postpericardiotomy syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal transplant failure | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory fume inhalation disorder | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sternal fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic renal injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulna fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention postoperative | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulvovaginal injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acetabulum fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol poisoning | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brachial plexus injury | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical vertebral fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery restenosis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gas poisoning | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal anastomotic haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyphaema | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc injury | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaw fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication circulatory | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematuria | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural hypotension | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural dizziness | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiation proctitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract procedural complication | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon rupture | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheal haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic arthritis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic intracranial haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular access site dissection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Hydrocele | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic cardiomyopathy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphatic malformation | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Angina pectoris | | | |
| subjects affected / exposed | 84 / 9027 (0.93%) | 106 / 9010 (1.18%) | |
| occurrences causally related to treatment / all | 0 / 89 | 0 / 107 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |
| subjects affected / exposed | 59 / 9027 (0.65%) | 69 / 9010 (0.77%) | |
| occurrences causally related to treatment / all | 0 / 63 | 0 / 73 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Cardiac failure | | | |
| subjects affected / exposed | 64 / 9027 (0.71%) | 54 / 9010 (0.60%) | |
| occurrences causally related to treatment / all | 2 / 67 | 0 / 61 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 48 / 9027 (0.53%) | 48 / 9010 (0.53%) | |
| occurrences causally related to treatment / all | 0 / 53 | 0 / 50 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 27 / 9027 (0.30%) | 23 / 9010 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 28 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 21 / 9027 (0.23%) | 20 / 9010 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 24 | 1 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 29 / 9027 (0.32%) | 19 / 9010 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 29 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 16 / 9027 (0.18%) | 14 / 9010 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 19 / 9027 (0.21%) | 14 / 9010 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 23 / 9027 (0.25%) | 14 / 9010 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 24 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Atrial flutter | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 15 / 9027 (0.17%) | 12 / 9010 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 13 / 9027 (0.14%) | 11 / 9010 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Pericarditis | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 10 / 9010 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 10 / 9010 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Coronary artery stenosis | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 9 / 9010 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 10 / 9027 (0.11%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure acute | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 12 / 9027 (0.13%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic cardiomyopathy | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Torsade de pointes | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dressler's syndrome | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postinfarction angina | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiac failure chronic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 9027 (0.04%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery perforation | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute left ventricular failure | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac tamponade | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ventricular thrombosis | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve stenosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus arrest | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve incompetence | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia supraventricular | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriospasm coronary | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial tachycardia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac asthma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac discomfort | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic coronary syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery dissection | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery insufficiency | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular dysfunction | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Low cardiac output syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve disease | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial rupture | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodal rhythm | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial haemorrhage | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prinzmetal angina | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulseless electrical activity | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Right ventricular failure | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus tachycardia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachyarrhythmia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anginal equivalent | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorder | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac dysfunction | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiorenal syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extrasystoles | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracardiac thrombus | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocarditis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial mass | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trifascicular block | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricle rupture | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Syncope | | | |
| subjects affected / exposed | 26 / 9027 (0.29%) | 23 / 9010 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 10 / 9027 (0.11%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |
| subjects affected / exposed | 10 / 9027 (0.11%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic encephalopathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular disorder | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic neuropathy | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Neuralgia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normal pressure hydrocephalus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinsonism | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Amnesia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphasia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal ganglia haemorrhage | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain oedema | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid sinus syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral artery stenosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 9027 (0.04%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cerebrovascular insufficiency | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic coma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness postural | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysarthria | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised tonic-clonic seizure | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic stroke | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic transformation stroke | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic encephalopathy | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monoparesis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post stroke epilepsy | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudoradicular syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiculopathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status epilepticus | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tension headache | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VIth nerve paralysis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amyotrophic lateral sclerosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain injury | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery aneurysm | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral atrophy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haematoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cerebral thrombosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dystonia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lethargy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (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 | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Partial seizures | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Restless legs syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral artery stenosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar insufficiency | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 39 / 9027 (0.43%) | 40 / 9010 (0.44%) | |
| occurrences causally related to treatment / all | 1 / 43 | 0 / 45 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 9 / 9010 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood loss anaemia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymph node pain | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normocytic anaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acquired haemophilia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia macrocytic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune haemolytic anaemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic disorder | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microcytic anaemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic infarction | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Vertigo positional | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden hearing loss | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular disorder | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness unilateral | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 4 / 9027 (0.04%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract nuclear | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye allergy | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Optic ischaemic neuropathy | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinopathy hypertensive | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blindness unilateral | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glaucoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lacrimation increased | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Purtscher retinopathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal detachment | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tolosa-Hunt syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 19 / 9027 (0.21%) | 13 / 9010 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Gastritis | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 10 / 9010 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9027 (0.03%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 12 / 9027 (0.13%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 2 / 15 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 9027 (0.07%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pancreatitis | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal polyp haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Ileus | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haemorrhage | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis haemorrhagic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9027 (0.03%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal stenosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| 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 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mallory-Weiss syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive pancreatitis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Vomiting | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 9027 (0.04%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dental caries | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric antral vascular ectasia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal polyp | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal vascular malformation haemorrhagic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic erosive gastritis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heyde's syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus paralytic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated inguinal hernia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal pseudo-obstruction | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine perforation | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis haemorrhagic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis necrotising | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Peptic ulcer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal hypertensive gastropathy | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haemorrhage | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute abdomen | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gastroparesis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea haemorrhagic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis haemorrhagic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocutaneous fistula | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food poisoning | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric polyps | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal angiodysplasia | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal erosion | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal obstruction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal toxicity | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haematoma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haemorrhage | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mechanical ileus | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric artery stenosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Noninfective sialoadenitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic atrophy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis relapsing | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reflux gastritis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal haemorrhage | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Skin and subcutaneous tissue disorders** | | | |
| Diabetic foot | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 2 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angioedema | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotic angiodermatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Panniculitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug eruption | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ingrowing nail | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash pruritic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin ulcer | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 66 / 9027 (0.73%) | 68 / 9010 (0.75%) | |
| occurrences causally related to treatment / all | 5 / 71 | 10 / 72 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Renal impairment | | | |
| subjects affected / exposed | 14 / 9027 (0.16%) | 15 / 9010 (0.17%) | |
| occurrences causally related to treatment / all | 1 / 17 | 2 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |
| subjects affected / exposed | 10 / 9027 (0.11%) | 14 / 9010 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 14 / 9027 (0.16%) | 12 / 9010 (0.13%) | |
| occurrences causally related to treatment / all | 1 / 14 | 1 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy toxic | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 11 / 9010 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 10 / 9010 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 8 / 9027 (0.09%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urinary | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal injury | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder disorder | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus bladder | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End stage renal disease | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelocaliectasis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal tubular necrosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral haemorrhage | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Azotaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Bladder diverticulum | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder tamponade | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urethral | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis erosive | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage urinary tract | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurogenic bladder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal infarct | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal salt-wasting syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vesical fistula | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Goitre | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaldosteronism | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenocortical insufficiency acute | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Bladder transitional cell carcinoma | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paget's disease of nipple | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal neoplasm | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma pancreas | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypopharyngeal cancer recurrent | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 15 / 9027 (0.17%) | 8 / 9010 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costochondritis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Compartment syndrome | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gouty arthritis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma muscle | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc space narrowing | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck pain | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid arthritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue necrosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral foraminal stenosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Flank pain | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint effusion | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myalgia | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyarthritis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal synovial cyst | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Pneumonia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 89 / 9027 (0.99%) | 97 / 9010 (1.08%) | |
| occurrences causally related to treatment / all | 0 / 93 | 0 / 99 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 4 | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 46 / 9027 (0.51%) | 52 / 9010 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 47 | 0 / 52 | |
| deaths causally related to treatment / all | 0 / 12 | 0 / 13 | |
| COVID-19 | | | |
| subjects affected / exposed | 48 / 9027 (0.53%) | 42 / 9010 (0.47%) | |
| occurrences causally related to treatment / all | 0 / 49 | 0 / 42 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 10 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 36 / 9027 (0.40%) | 37 / 9010 (0.41%) | |
| occurrences causally related to treatment / all | 1 / 39 | 0 / 38 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 26 / 9027 (0.29%) | 26 / 9010 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 3 | |
| Urosepsis | | | |
| subjects affected / exposed | 8 / 9027 (0.09%) | 12 / 9010 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 12 / 9010 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cellulitis | | | |
| subjects affected / exposed | 17 / 9027 (0.19%) | 9 / 9010 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 9027 (0.07%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 23 / 9027 (0.25%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 23 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 12 | 0 / 3 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 6 / 9010 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 5 / 9027 (0.06%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 9027 (0.04%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 7 / 9027 (0.08%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia aspiration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 9027 (0.07%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess limb | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis infective | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral discitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmic herpes zoster | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parapharyngeal space infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia klebsiella | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung abscess | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary sepsis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acarodermatitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortitis syphilitic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis perforated | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis infective | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Babesiosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial sepsis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis infective | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chikungunya virus infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complicated appendicitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronavirus pneumonia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dengue fever | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related sepsis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis intestinal haemorrhagic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysematous cystitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterococcal sepsis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis bacterial | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helicobacter infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis E | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected skin ulcer | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella sepsis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Klebsiella urinary tract infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site joint infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle abscess | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasopharyngitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis acute | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic abscess | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia pneumococcal | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia staphylococcal | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis chronic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal abscess | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Respiratory tract infection bacterial | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salmonella sepsis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sternitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis septic | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth abscess | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection enterococcal | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular access site infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular neuronitis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess neck | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atypical pneumonia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial prostatitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Citrobacter sepsis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis klebsiella | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus colitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea infectious | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis enterococcal | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterobacter pneumonia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelothrix sepsis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia sepsis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Furuncle | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gas gangrene | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis salmonella | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Giardiasis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin abscess | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helicobacter gastritis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis B | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster disseminated | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 3 / 9027 (0.03%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney infection | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotising fasciitis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis externa | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritoneal abscess | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia acinetobacter | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pneumonia legionella | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-acute COVID-19 syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyoderma | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyonephrosis | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyuria | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal abscess | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin infection | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal infection | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strongyloidiasis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (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 | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular device infection | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 12 / 9010 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 14 / 9027 (0.16%) | 10 / 9010 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 9 / 9010 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 6 / 9027 (0.07%) | 7 / 9010 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9027 (0.03%) | 5 / 9010 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 9 / 9027 (0.10%) | 4 / 9010 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gout | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 3 / 9010 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 4 / 9027 (0.04%) | 2 / 9010 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abnormal loss of weight | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cachexia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diabetic metabolic decompensation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Euglycaemic diabetic ketoacidosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperinsulinaemic hypoglycaemia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 3 / 9027 (0.03%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ketoacidosis | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| 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 | 0 / 9027 (0.00%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic acidosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9027 (0.02%) | 1 / 9010 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 2 / 9027 (0.02%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypernatraemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypophosphataemia | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malnutrition | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 1 / 9027 (0.01%) | 0 / 9010 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| **Non-serious adverse events** | Placebo | CSL112 | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 9027 (0.00%) | 0 / 9010 (0.00%) | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 10 September 2019 | The list below describes key changes to the Clinical Study Protocol:<br>• Modified the primary endpoint to include all MI events instead of only type 1 (spontaneous) MI events.<br>• In the original protocol (dated 23 January 2018) for Inclusion Criteria 6, participants were required to have at least 1 of the following established risk factors: age >= 65 years, prior history of MI, diabetes mellitus requiring pharmacotherapy, or peripheral artery disease. Modification of Inclusion Criteria 6 utilized the same risk factors but instead required the presence of diabetes mellitus requiring pharmacotherapy, or 2 or more of the following: age >= 65 years, prior history of MI, and peripheral artery disease. This modification to Inclusion Criteria 6 was implemented to limit enrollment to participants that were at an even higher risk of an early recurrent cardiovascular event.<br>• Included additional secondary and exploratory endpoints.<br>• Specified that the 70% interim analysis would not be performed if the expected IDMC review of the interim analysis was less than 2 months prior to the anticipated completion of enrollment.<br>• Included the option to limit the number of participants enrolled with a specific index MI type (ie, STEMI or NSTEMI).<br>• Added updated nonclinical data as well as clinical data from Study CSL112_1002.<br>• Modified wording to provide clarifications and improve protocol compliance. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported