

**Clinical trial results:****A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effect of Long-Term Treatment with BELVIQ (lorcaserin HCl) on the Incidence of Major Adverse Cardiovascular Events and Conversion to Type 2 Diabetes Mellitus in Obese and Overweight Subjects with Cardiovascular Disease or Multiple Cardiovascular Risk Factors****Summary**

| | |
|--------------------------|----------------|
| EudraCT number | 2013-000324-34 |
| Trial protocol | PL |
| Global end of trial date | 14 May 2018 |

Results information

| | |
|--------------------------------|---|
| Result version number | v2 (current) |
| This version publication date | 13 July 2019 |
| First version publication date | 30 May 2019 |
| Version creation reason | <ul style="list-style-type: none">• Changes to summary attachments Updates to be made in the time frame of 2 endpoints and 1 analysis population description. |

Trial information**Trial identification**

| | |
|-----------------------|-----------------|
| Sponsor protocol code | APD356-G000-401 |
|-----------------------|-----------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02019264 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Eisai Ltd. |
| Sponsor organisation address | European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, United Kingdom, AL10 9SN |
| Public contact | Eisai Medical Information, Eisai Ltd., +1 888-274-2378, esi_medinfo@eisai.com |
| Scientific contact | Eisai Medical Information, Eisai Ltd., +1 888-274-2378, esi_medinfo@eisai.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 | 14 May 2018 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 14 May 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that, in obese and overweight subjects with cardiovascular (CV) disease and/or multiple CV risk factors, lorcaserin hydrochloride (HCl) 10 milligram (mg) administered twice daily (BID) does not increase the incidence of major adverse cardiovascular events (MACE) (myocardial infarction [MI], or stroke, or CV death) compared to placebo, with a noninferiority margin for the hazard ratio (HR) of 1.4, and in obese and overweight subjects with CV disease and/or multiple CV risk factors, lorcaserin HCl 10 mg BID reduces the incidence of MACE+ (MACE or hospitalization for unstable angina or heart failure [HF], or any coronary revascularization) compared to placebo

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures (SOPs) of the sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following:

- Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008)
- International Council on Harmonisation (ICH) E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board (IRB) regulations and applicable sections of US 21 CFR Part 312
- European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions were reported, as required, to the Competent Authorities of all involved EU member states.
- Article 14, Paragraph 3, and Article 80-2 of the Pharmaceutical Affairs Law (Law No. 145, 1960) for studies conducted in Japan, in addition to Japan's GCP Subject Information and Informed Consent.

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 24 January 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|----------------|
| Country: Number of subjects enrolled | Australia: 535 |
| Country: Number of subjects enrolled | Bahamas: 10 |
| Country: Number of subjects enrolled | Canada: 1165 |
| Country: Number of subjects enrolled | Chile: 107 |

| | |
|--------------------------------------|---------------------|
| Country: Number of subjects enrolled | Mexico: 255 |
| Country: Number of subjects enrolled | New Zealand: 316 |
| Country: Number of subjects enrolled | Poland: 985 |
| Country: Number of subjects enrolled | United States: 8627 |
| Worldwide total number of subjects | 12000 |
| EEA total number of subjects | 985 |

Notes:

Subjects enrolled per age group

| | |
|---|------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 6257 |
| From 65 to 84 years | 5699 |
| 85 years and over | 44 |

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study at investigative sites in the United States, Bahamas, Canada, Mexico, Chile, New Zealand, Poland, and Australia from 24 Jan 2014 to 14 May 2018.

Pre-assignment

Screening details:

A total of 14,673 subjects were screened and enrolled, of which 2673 subjects were screen failures and 12,000 were randomized to receive lorcaserin HCl or placebo.

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 |

Arms

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

Arm description:

Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.

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

Dosage and administration details:

Lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.

| | |
|------------------|------------------|
| Arm title | Lorcaserin 10 mg |
|------------------|------------------|

Arm description:

Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.

| | |
|--|----------------|
| Arm type | Experimental |
| Investigational medicinal product name | Lorcaserin |
| Investigational medicinal product code | |
| Other name | APD356, BELVIQ |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.

| Number of subjects in period 1 | Placebo | Lorcaserin 10 mg |
|---------------------------------------|---------|------------------|
| Started | 6000 | 6000 |
| Completed | 5752 | 5793 |
| Not completed | 248 | 207 |
| Not Treated | 6 | 4 |
| Withdrawal by subjects | 142 | 117 |
| Lost to follow-up | 50 | 47 |
| Missing | 14 | 11 |
| Administrative reason | 36 | 28 |

Baseline characteristics

Reporting groups

| | |
|--|------------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months. | |
| Reporting group title | Lorcaserin 10 mg |
| Reporting group description: | |
| Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months. | |

| Reporting group values | Placebo | Lorcaserin 10 mg | Total |
|---|---------|------------------|-------|
| Number of subjects | 6000 | 6000 | 12000 |
| Age categorical Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 63.7 | 63.5 | |
| standard deviation | ± 8.31 | ± 8.33 | - |
| Gender categorical Units: Subjects | | | |
| Female | 2186 | 2112 | 4298 |
| Male | 3814 | 3888 | 7702 |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 536 | 502 | 1038 |
| Not Hispanic or Latino | 5464 | 5498 | 10962 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 21 | 26 | 47 |
| Asian | 74 | 85 | 159 |
| Native Hawaiian or Other Pacific Islander | 23 | 30 | 53 |
| Black or African American | 466 | 454 | 920 |
| White | 5331 | 5309 | 10640 |
| More than one race | 85 | 96 | 181 |
| Unknown or Not Reported | 0 | 0 | 0 |

End points

End points reporting groups

| | |
|--|------------------|
| Reporting group title | Placebo |
| Reporting group description: | |
| Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months. | |
| Reporting group title | Lorcaserin 10 mg |
| Reporting group description: | |
| Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months. | |

Primary: Time From Randomization to First Occurrence of Major Adverse Cardiovascular Events (MACE) at Interim Analysis

| | |
|--|---|
| End point title | Time From Randomization to First Occurrence of Major Adverse Cardiovascular Events (MACE) at Interim Analysis |
| End point description: | |
| The MACE events involved MI, stroke, or CV death. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set using the intent-to-treat (ITT) set, events were counted that occurred while subjects were on and off treatment. Subjects with no events were censored at their last study contact or at the visit following sponsor notification of study completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects. | |
| End point type | Primary |
| End point timeframe: | |
| Baseline up to Month 42 | |

| End point values | Placebo | Lorcaserin 10 mg | | |
|----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6000 | 6000 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[1] |
| P-value | < 0.0001 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.005 |

| | |
|---------------------|---------------|
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.842 |
| upper limit | 1.198 |

Notes:

[1] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. MACE met non-inferiority when the one-sided upper bound of 97.5% confidence interval of the HR was less than (<) 1.4 (the non-inferiority margin).

Primary: Time From Randomization to First Occurrence of MACE+

| | |
|--|--|
| End point title | Time From Randomization to First Occurrence of MACE+ |
| End point description: | |
| The MACE+ events involved MI, stroke, or CV death or hospitalization for unstable angina or heart failure (HF), or any coronary revascularization. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set used the ITT set, events were counted that occurred while subjects were on and off treatment. Subjects with no events were censored at their last study contact or at the visit following Sponsor Notification of Study Completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects. | |
| End point type | Primary |
| End point timeframe: | |
| Baseline up to end of study (Month 56) | |

| End point values | Placebo | Lorcaserin 10 mg | | |
|----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6000 | 6000 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[2] |
| P-value | = 0.5464 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.969 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.873 |
| upper limit | 1.074 |

Notes:

[2] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Time From Randomization to Conversion to Type 2 Diabetes Mellitus (T2DM) for Subjects With Prediabetes at Baseline

| | |
|-----------------|--|
| End point title | Time From Randomization to Conversion to Type 2 Diabetes Mellitus (T2DM) for Subjects With Prediabetes at Baseline |
|-----------------|--|

End point description:

Time from randomization to conversion to T2DM was defined as first occurrence of any component of the 2013 American Diabetes Association (ADA) Diagnostic Criteria (ADA, 2013) in subjects with prediabetes at baseline. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula.

Prediabetes and total time analysis set used ITT set: without a history of any type of diabetes and who were prediabetic at baseline; events were counted that occurred while subjects were on, off treatment; subjects with no events were censored at last study contact/at visit after notification of study completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

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

End point timeframe:

Baseline up to end of study (Month 56)

| End point values | Placebo | Lorcaserin 10 mg | | |
|----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1976 | 2015 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 3991 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[3] |
| P-value | = 0.038 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.807 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.659 |
| upper limit | 0.988 |

Notes:

[3] - Hazard ratio was based on Cox-regression model including treatment as covariate.

Secondary: Time From Randomization to First Occurrence of the Individual Components of MACE+

| | |
|-----------------|---|
| End point title | Time From Randomization to First Occurrence of the Individual Components of MACE+ |
|-----------------|---|

End point description:

The MACE+ events involved MI, stroke, or CV death or hospitalization for unstable angina or HF, or any coronary revascularization. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set used the ITT set, events counted occurred while subjects were on and off treatment. Subjects with no events were censored at last study contact or at the visit following Sponsor Notification of Study Completion, whichever first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

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

End point timeframe:

Baseline up to end of study (Month 56)

| End point values | Placebo | Lorcaserin 10 mg | | |
|---|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6000 | 6000 | | |
| Units: days | | | | |
| arithmetic mean (confidence interval 95%) | | | | |
| MI | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| Stroke | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CV death | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| Hospitalization for unstable angina | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| HF | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| Coronary revascularization | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|--------------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[4] |
| P-value | = 0.0001 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.991 |

| | |
|---------------------|---------------|
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.824 |
| upper limit | 1.191 |

Notes:

[4] - MI: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. 97.5% confidence interval refers to the upper limit of the displayed 2-sided 95% confidence interval.

| | |
|---|--------------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[5] |
| P-value | = 0.0005 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.856 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.639 |
| upper limit | 1.145 |

Notes:

[5] - Time to Stroke: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. 97.5% confidence interval refers to the upper limit of the displayed 2-sided 95% confidence interval.

| | |
|---|--------------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[6] |
| P-value | = 0.0262 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.045 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.778 |
| upper limit | 1.404 |

Notes:

[6] - Cardiovascular Death: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates. 97.5% confidence interval refers to the upper limit of the displayed 2-sided 95% confidence interval.

| | |
|-----------------------------------|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |

| | |
|---|----------------------------|
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[7] |
| P-value | = 0.3243 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.163 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.861 |
| upper limit | 1.571 |

Notes:

[7] - Hospitalization for Unstable Angina: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[8] |
| P-value | = 0.6758 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.952 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.757 |
| upper limit | 1.197 |

Notes:

[8] - HF: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[9] |
| P-value | = 0.7817 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.981 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.856 |
| upper limit | 1.125 |

Notes:

[9] - Coronary Revascularization: Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Time From Randomization to Event of All-cause Mortality

| | |
|---|---|
| End point title | Time From Randomization to Event of All-cause Mortality |
| End point description: | |
| The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The total time analysis set used the ITT set, events were counted that occurred while subjects were on and off treatment. Subjects with no events were censored at their last study contact or at the visit following Sponsor Notification of Study Completion, whichever occurred first. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline up to end of study (Month 56) | |

| End point values | Placebo | Lorcaserin 10 mg | | |
|----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6000 | 6000 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.4212 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.082 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.893 |
| upper limit | 1.31 |

Secondary: Time From Randomization to Conversion to Normal Glucose Homeostasis in Subjects With Prediabetes at Baseline

| | |
|-----------------|--|
| End point title | Time From Randomization to Conversion to Normal Glucose Homeostasis in Subjects With Prediabetes at Baseline |
|-----------------|--|

End point description:

Normal glucose homeostasis was defined as glycosylated hemoglobin (HbA1c) less than or equal to (\leq) 5.6% and fasting plasma glucose (FPG) < 100 milligram per deciliter (mg/dL) without any antidiabetic treatment. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The prediabetes analysis set included all subjects in the ITT set without a history of any type of diabetes and who were prediabetic at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of

censored subjects.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline up to end of study (Month 56) | |

| End point values | Placebo | Lorcaserin 10 mg | | |
|----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1976 | 2015 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|-----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 3991 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[10] |
| P-value | = 0.181 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.124 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.947 |
| upper limit | 1.333 |

Notes:

[10] - Hazard ratio was based on a Cox regression model including treatment as covariate.

Secondary: Time From Randomization to Conversion to T2DM for Subjects Without Any Type of Diabetes at Baseline

| | |
|--|---|
| End point title | Time From Randomization to Conversion to T2DM for Subjects Without Any Type of Diabetes at Baseline |
| End point description: | |
| The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The nondiabetes analysis set included all subjects in the ITT set without a history of any type of diabetes at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline up to end of study (Month 56) | |

| End point values | Placebo | Lorcaserin 10 mg | | |
|----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2569 | 2615 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| Statistical analysis title | Placebo, Lorcaserin 10 mg |
|---|-----------------------------|
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 5184 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[11] |
| P-value | = 0.0116 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.773 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.633 |
| upper limit | 0.944 |

Notes:

[11] - Hazard ratio was based on a Cox regression model including treatment as covariate.

Secondary: Change From Baseline in HbA1c at Month 6 in Subjects With T2DM at Baseline

| | |
|------------------------|--|
| End point title | Change From Baseline in HbA1c at Month 6 in Subjects With T2DM at Baseline |
| End point description: | The T2DM analysis set included all subjects in the ITT set who had T2DM at baseline. Here "n" was the T2DM analysis set where data was available at specified time points. |
| End point type | Secondary |
| End point timeframe: | Baseline, and Month 6 |

| End point values | Placebo | Lorcaserin 10 mg | | |
|--------------------------------------|-----------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3403 | 3362 | | |
| Units: percentage of HbA1c | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n=3403, 3362) | 6.99 (± 1.066) | 7.01 (± 1.082) | | |
| Change at Month 6 (n=3087, 3035) | 0.06 (± 0.777) | -0.33 (± 0.785) | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 6765 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[12] |
| Method | ANCOVA |
| Parameter estimate | Least square (LS) Mean Difference (Net) |
| Point estimate | -0.39 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.43 |
| upper limit | -0.35 |

Notes:

[12] - P-value was based on analysis of covariance (ANCOVA) model with treatment and stratification variable (presence of established CV disease or CV risk factors without established CV disease) as factors, and baseline HbA1c, as a covariate.

Secondary: Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in All Subjects

| | |
|-----------------|---|
| End point title | Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in All Subjects |
|-----------------|---|

End point description:

New onset/worsening of existing renal impairment was first occurrence of any events: microalbuminuria and macroalbuminuria, worsening albuminuria (microalbuminuria at Baseline developed macroalbuminuria, ACR increased $\geq 30\%$ from Baseline during treatment), newly developed chronic kidney disease (CKD) or worsening of CKD (based on National Kidney Foundation [NKF] Guidelines [2002]) worsened to higher CKD stages during treatment), or doubling of serum creatinine (creatinine value at least 2 times Baseline value and ≥ 1.5 mg/dL during treatment.), or any of following: end-stage renal disease, renal transplant, renal death. Outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. ITT set included all randomized subjects regardless of whether they took study drug or not. This set was the same as full analysis set. "99999": Median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

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

End point timeframe:

Baseline up to end of study (Month 56)

| | | | | |
|----------------------------------|------------------------|------------------------|--|--|
| End point values | Placebo | Lorcaserin 10 mg | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6000 | 6000 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|-----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 12000 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[13] |
| P-value | = 0.0054 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.869 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.787 |
| upper limit | 0.959 |

Notes:

[13] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With Prediabetes at Baseline

| | |
|-----------------|--|
| End point title | Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With Prediabetes at Baseline |
|-----------------|--|

End point description:

New onset/worsening of existing renal impairment was first occurrence of any events: microalbuminuria and macroalbuminuria, worsening albuminuria (microalbuminuria at Baseline developed macroalbuminuria, ACR increased $\geq 30\%$ from baseline during treatment), CKD as per NKF Guidelines [2002]) or worsening of CKD (CKD Stage1/higher as per NKF Guidelines [2002] worsened to higher CKD stages during treatment), or doubling serum creatinine(creatinine value at least twice baseline value and ≥ 1.5 mg/dL during treatment.), or any of: end stage renal disease, renal transplant, renal death. Outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. ITT set included all subjects without a history of any type of diabetes and were prediabetic at baseline. This set was the same as full analysis set. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

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

End point timeframe:

Baseline up to end of study (Month 56)

| | | | | |
|----------------------------------|------------------------|------------------------|--|--|
| End point values | Placebo | Lorcaserin 10 mg | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1976 | 2015 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|-----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 3991 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[14] |
| P-value | = 0.3661 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.904 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.727 |
| upper limit | 1.125 |

Notes:

[14] - Hazard ratio on a Cox regression model including treatment as covariate.

Secondary: Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With T2DM at Baseline

| | |
|-----------------|---|
| End point title | Time From Randomization to Event of New Onset Renal Impairment or Worsening Existing Renal Impairment in Subjects With T2DM at Baseline |
|-----------------|---|

End point description:

New onset/worsening of existing renal impairment was first occurrence of any events: microalbuminuria and macroalbuminuria, worsening albuminuria (microalbuminuria at baseline developed macroalbuminuria, ACR increased $\geq 30\%$ from baseline during treatment), CKD as per NKF Guidelines [2002]) or worsening of CKD (CKD Stage 1/higher as per NKF Guidelines [2002] worsened to higher CKD stages during treatment), or doubling of serum creatinine (creatinine value at least 2 times baseline value and ≥ 1.5 mg/dL during treatment.), or any of the following: end-stage renal disease, renal transplant, renal death. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The T2DM analysis set had all subjects in the ITT set who had T2DM at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects.

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

End point timeframe:

Baseline up to end of study (Month 56)

| | | | | |
|----------------------------------|------------------------|------------------------|--|--|
| End point values | Placebo | Lorcaserin 10 mg | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3403 | 3362 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 6765 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0082 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.855 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.762 |
| upper limit | 0.96 |

Secondary: Time From Randomization to Event of Improvement in Renal Function in Subjects With T2DM at Baseline

| | |
|--|--|
| End point title | Time From Randomization to Event of Improvement in Renal Function in Subjects With T2DM at Baseline |
| End point description: | Improvement in renal function: first occurrence of regression of albuminuria/regression of CKD. Regression of albuminuria: when subjects with macroalbuminuria at baseline developed microalbuminuria or nonalbuminuria, or subjects with microalbuminuria at baseline became nonalbuminuric, and ACR value decreased $\geq 30\%$ from previous assessment in treatment. Regression of CKD: when subjects with CKD Stage 1/higher at baseline improved to normal/lower stages by NKF guidelines in treatment. The outcome data was assessed using Kaplan-Meier estimate and Greenwood Formula. The T2DM analysis set included all subjects in ITT set who had T2DM at baseline. Here "99999" refers to median time and 95% confidence interval which could not be calculated since quartile was not estimable due to higher number of censored subjects. |
| End point type | Secondary |
| End point timeframe: | |
| Baseline up to end of study (Month 56) | |

| End point values | Placebo | Lorcaserin 10 mg | | |
|----------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3403 | 3362 | | |
| Units: days | | | | |
| median (confidence interval 95%) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

Statistical analyses

| Statistical analysis title | Placebo, Lorcaserin 10 mg |
|---|-----------------------------|
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 6765 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[15] |
| P-value | = 0.0297 |
| Method | Primary Analytic Method |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.182 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.017 |
| upper limit | 1.375 |

Notes:

[15] - Hazard ratio was based on Cox-regression model including treatment and CV strata as covariates.

Secondary: Percentage of Subjects Who Met FDA-Defined Valvulopathy in Echocardiographically Determined Heart Valve Changes

| End point title | Percentage of Subjects Who Met FDA-Defined Valvulopathy in Echocardiographically Determined Heart Valve Changes |
|---|---|
| End point description: | |
| The FDA-defined valvulopathy analysis set included all subjects in the ITT set without FDA-defined valvulopathy at baseline. Here "n" was the FDA-defined valvulopathy analysis set where data was available at specified time point. | |
| End point type | Secondary |
| End point timeframe: | |
| Months 6 and 12 | |

| End point values | Placebo | Lorcaserin 10 mg | | |
|-------------------------------|-----------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1935 | 1925 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Month 6 (n=1683, 1681) | 1.4 | 2.1 | | |
| Month 12 (n=1564, 1579) | 1.5 | 1.8 | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 3860 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.5015 ^[16] |
| Method | Primary Analytic Method |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.21 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.69 |
| upper limit | 2.11 |

Notes:

[16] - P-value was based on logistic regression including treatment as a factor and baseline body mass index (BMI) as a covariate.

Secondary: Percentage of Subjects With FDA-Defined Valvulopathy at Baseline Who Demonstrated Worsened FDA-Defined Valvulopathy

| | |
|-----------------|---|
| End point title | Percentage of Subjects With FDA-Defined Valvulopathy at Baseline Who Demonstrated Worsened FDA-Defined Valvulopathy |
|-----------------|---|

End point description:

The ITT analysis set in subjects with FDA-defined valvulopathy at baseline was used. Here "n" was the ITT analysis set in subjects with FDA-defined valvulopathy at baseline where data was available at specified time point.

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

End point timeframe:

Months 6 and 12

| | | | | |
|-------------------------------|-----------------|------------------|--|--|
| End point values | Placebo | Lorcaserin 10 mg | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 228 | 225 | | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Month 6 (n=194, 201) | 2.1 | 3.5 | | |
| Month 12 (n=180, 189) | 1.7 | 2.1 | | |

Statistical analyses

| | |
|---|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Placebo v Lorcaserin 10 mg |
| Number of subjects included in analysis | 453 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.7249 ^[17] |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.31 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.29 |
| upper limit | 5.98 |

Notes:

[17] - P-value was based on logistic regression including treatment as a factor and baseline BMI as a covariate.

Secondary: Change From Baseline in Echocardiographically-Determined Pulmonary Arterial Systolic Pressure

| | |
|-----------------|---|
| End point title | Change From Baseline in Echocardiographically-Determined Pulmonary Arterial Systolic Pressure |
|-----------------|---|

End point description:

The ITT analysis set-subjects in ECHO substudy included all randomized subjects regardless of whether they took study drug or not. Here "n" was the ITT analysis set-subjects in the ECHO substudy, where data was available at specified time points.

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

End point timeframe:

Baseline, Month 12

| End point values | Placebo | Lorcaserin 10 mg | | |
|--------------------------------------|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2167 | 2151 | | |
| Units: Millimeter of mercury (mmHg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n=1368, 1358) | 26.4354 (± 7.66312) | 26.2029 (± 7.54123) | | |
| Change at Month 12 (n=882, 893) | -0.6418 (± 6.81716) | -0.8223 (± 7.23770) | | |

Statistical analyses

| | |
|-----------------------------------|----------------------------|
| Statistical analysis title | Placebo, Lorcaserin 10 mg |
| Comparison groups | Lorcaserin 10 mg v Placebo |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 4318 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.2976 ^[18] |
| Method | Mixed-effects model |
| Parameter estimate | Mean difference (net) |
| Point estimate | -0.9036 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.2908 |
| upper limit | -0.5163 |

Notes:

[18] - P value was based on a mixed-effects model (unstructured covariance matrix) with repeated measures with treatment, month and treatment by month interaction as factors and baseline pulmonary arterial systolic pressure and baseline BMI as covariates.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline up to 30 days after last dose of study drug (approximately 56 months)

Adverse event reporting additional description:

Adverse events were collected for the subject who were in the safety analysis set (all subjects who received at least 1 dose of study drug and had at least one post dose safety assessment).

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 19.0 |
|--------------------|------|

Reporting groups

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

Reporting group description:

Subjects received lorcaserin HCL placebo-matching, tablets, orally, twice daily for up to 52 months.

| | |
|-----------------------|------------------|
| Reporting group title | Lorcaserin 10 mg |
|-----------------------|------------------|

Reporting group description:

Subjects received lorcaserin HCL 10 mg, tablets, orally, twice daily for up to 52 months.

| Serious adverse events | Placebo | Lorcaserin 10 mg | |
|---|-------------------------|-------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2021 / 5992 (33.73%) | 1974 / 5995 (32.93%) | |
| number of deaths (all causes) | 202 | 219 | |
| number of deaths resulting from adverse events | 121 | 132 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute leukaemia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Adenocarcinoma gastric | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of appendix | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Adenocarcinoma of colon | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma pancreas | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 1 / 1 | |
| Adrenal adenoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal gland cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal neoplasm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiomyolipoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendix cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Atypical fibroxanthoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| B-cell lymphoma stage III | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign gastric neoplasm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of ampulla of Vater | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of bladder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of thyroid gland | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign renal neoplasm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign small intestinal neoplasm | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary neoplasm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer recurrent | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma recurrent | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain cancer metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Brain neoplasm | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer in situ | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix carcinoma stage IV | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cholangiocarcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Choroid melanoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Choroid neoplasm | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Chronic myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clear cell renal cell carcinoma | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon adenoma | | | |
| subjects affected / exposed | 11 / 5992 (0.18%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 2 / 12 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer stage IV | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Diffuse large B-cell lymphoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Endometrial adenocarcinoma | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 5 / 5992 (0.08%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial cancer | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extranodal marginal zone B-cell lymphoma (MALT type) | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibroadenoma of breast | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibroma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Follicular thyroid cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer stage 0 | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stromal tumour | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Glioblastoma multiforme | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Hepatic cancer metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hodgkin's disease | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal papillary mucinous neoplasm | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal papillary-mucinous carcinoma of pancreas | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal papilloma of breast | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive breast carcinoma | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 8 / 5992 (0.13%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Keratoacanthoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney angiomyolipoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipoma | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Lung adenocarcinoma stage 0 | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma stage IV | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Lung cancer metastatic | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Lung carcinoma cell type unspecified stage III | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 13 / 5995 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung squamous cell carcinoma stage II | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoma | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 17 / 5992 (0.28%) | 20 / 5995 (0.33%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma in situ | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma stage I | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant neoplasm of ampulla of Vater | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Malignant neoplasm of spinal cord | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant neoplasm of unknown primary site | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant sweat gland neoplasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melanocytic naevus | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma benign | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to liver | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Metastases to lung | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to lymph nodes | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastasis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic carcinoma of the bladder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastatic malignant melanoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastatic renal cell carcinoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mucinous cystadenocarcinoma ovary | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Mycosis fungoides | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myxofibrosarcoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasopharyngeal cancer | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm prostate | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm skin | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine tumour | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodular melanoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 5992 (0.05%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Non-small cell lung cancer stage I | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal adenocarcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal adenocarcinoma metastatic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal carcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Oropharyngeal cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian adenoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cancer metastatic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pancreatic carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 4 | |
| Pancreatic carcinoma metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | |
| Pancreatic neuroendocrine tumour | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary serous endometrial carcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary thyroid cancer | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritoneal carcinoma metastatic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pharyngeal cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pituitary tumour benign | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma cell myeloma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Polycythaemia vera | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 51 / 5992 (0.85%) | 50 / 5995 (0.83%) | |
| occurrences causally related to treatment / all | 0 / 51 | 1 / 50 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Prostate cancer recurrent | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Prostate cancer stage II | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectosigmoid cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland adenoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland cancer | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin squamous cell carcinoma metastatic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell carcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Small cell lung cancer | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer extensive stage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Small cell lung cancer metastatic | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 head and neck | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Squamous cell carcinoma of lung | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the oral cavity | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the tongue | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue neoplasm malignant stage unspecified | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsil cancer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteral neoplasm | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral cancer | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval cancer stage 0 | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Waldenstrom's macroglobulinaemia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 11 / 5992 (0.18%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic dissection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Aortic stenosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 7 / 5992 (0.12%) | 14 / 5995 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial stenosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Arteriovenous fistula | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Circulatory collapse | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 13 / 5992 (0.22%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dry gangrene | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 8 / 5995 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 10 / 5992 (0.17%) | 16 / 5995 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemic shock | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Iliac artery disease | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermittent claudication | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemia | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leriche syndrome | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoedema | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant hypertension | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microscopic polyangiitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 11 / 5992 (0.18%) | 14 / 5995 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery dissection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral ischaemia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral venous disease | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Poor peripheral circulation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reperfusion injury | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian artery stenosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis superficial | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Adverse drug reaction | | | |

| | | |
|---|-------------------|-------------------|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 5 / 5992 (0.08%) | 9 / 5995 (0.15%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardiac death | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 |
| Chest discomfort | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 6 / 5995 (0.10%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Chest pain | | |
| subjects affected / exposed | 21 / 5992 (0.35%) | 16 / 5995 (0.27%) |
| occurrences causally related to treatment / all | 0 / 22 | 0 / 16 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Complication associated with device | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cyst | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Death | | |
| subjects affected / exposed | 12 / 5992 (0.20%) | 16 / 5995 (0.27%) |
| occurrences causally related to treatment / all | 1 / 12 | 2 / 16 |
| deaths causally related to treatment / all | 1 / 12 | 2 / 16 |
| Drug withdrawal syndrome | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exercise tolerance decreased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal complication associated with device | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia pain | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothermia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired healing | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site erosion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated hernia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infusion site extravasation | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised oedema | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 / 5992 (0.03%) | 0 / 5995 (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 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Non-cardiac chest pain | | | |

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|---|--------------------|--------------------|--|
| subjects affected / exposed | 132 / 5992 (2.20%) | 133 / 5995 (2.22%) | |
| occurrences causally related to treatment / all | 0 / 153 | 1 / 164 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stent-graft endoleak | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden cardiac death | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Sudden death | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Systemic inflammatory response syndrome | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent occlusion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent restenosis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent thrombosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic shock | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |

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|---|-------------------|------------------|--|
| Convalescent | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Spousal abuse | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Acquired hydrocele | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adnexa uteri mass | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 10 / 5992 (0.17%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast enlargement | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast fibrosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast hyperplasia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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| Breast pain | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast ulceration | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystocele | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erectile dysfunction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Female genital tract fistula | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Mastoptosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis noninfective | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Organic erectile dysfunction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic prolapse | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Penis disorder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postmenopausal haemorrhage | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Priapism | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 2 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatism | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal haematocoele | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine polyp | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine prolapse | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal prolapse | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute pulmonary oedema | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory distress syndrome | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 28 / 5992 (0.47%) | 35 / 5995 (0.58%) | |
| occurrences causally related to treatment / all | 1 / 31 | 0 / 37 | |
| deaths causally related to treatment / all | 1 / 3 | 0 / 5 | |
| Allergic bronchitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atelectasis | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis chronic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchospasm | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 43 / 5992 (0.72%) | 39 / 5995 (0.65%) | |
| occurrences causally related to treatment / all | 0 / 53 | 0 / 58 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 38 / 5992 (0.63%) | 27 / 5995 (0.45%) | |
| occurrences causally related to treatment / all | 1 / 40 | 0 / 27 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 11 / 5992 (0.18%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysema | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiccups | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercapnia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 8 / 5995 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Idiopathic pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal granuloma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal mass | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung disorder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Mediastinal haematoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal obstruction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal polyps | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive airways disorder | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal fistula | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pickwickian syndrome | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 10 / 5992 (0.17%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleurisy | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| 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 | 4 / 5992 (0.07%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 26 / 5992 (0.43%) | 20 / 5995 (0.33%) | |
| occurrences causally related to treatment / all | 1 / 27 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pulmonary granuloma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 14 / 5995 (0.23%) | |
| occurrences causally related to treatment / all | 4 / 14 | 1 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 8 / 5992 (0.13%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Pulmonary sarcoidosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 14 / 5995 (0.23%) | |
| occurrences causally related to treatment / all | 1 / 14 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillar hypertrophy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Agitation | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol abuse | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anger | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional state | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Depression | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hallucination | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Insomnia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Major depression | | | |

| | | | |
|--|------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental disorder due to a general medical condition | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nightmare | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic stress disorder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic disorder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Somatic delusion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 3 / 4 | 6 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 dislocation | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device failure | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device loosening | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device malfunction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device pacing issue | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lead dislodgement | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct obstruction | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stone | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary dyskinesia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 1 / 14 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis chronic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 24 / 5992 (0.40%) | 14 / 5995 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 25 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis obstructive | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic hepatic failure | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cirrhosis alcoholic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cryptogenic cirrhosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cirrhosis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Hepatic cyst | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic function abnormal | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic mass | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic vascular thrombosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver disorder | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver injury | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-alcoholic fatty liver | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal vein thrombosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Ammonia increased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic bruit | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood calcium decreased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose increased | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood immunoglobulin G decreased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium increased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure increased | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood sodium increased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood urea increased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Body temperature increased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac stress test abnormal | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulation test abnormal | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| ECG signs of myocardial ischaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ejection fraction decreased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram QT prolonged | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram ST segment depression | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram abnormal | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glycosylated haemoglobin increased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart rate decreased | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio abnormal | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test increased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| N-terminal prohormone brain natriuretic peptide increased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oxygen saturation decreased | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic specific antigen increased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary arterial pressure increased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin T increased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin increased | | | |
| subjects affected / exposed | 8 / 5992 (0.13%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| White blood cell count increased | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Abdominal injury | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental overdose | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol poisoning | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia postoperative | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic ulcer haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Animal bite | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial bypass thrombosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial injury | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder injury | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain contusion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiac contusion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac valve replacement complication | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cartilage injury | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 2 / 5992 (0.03%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest injury | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis radiation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delayed recovery from anaesthesia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural haematoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial bones fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 15 / 5992 (0.25%) | 21 / 5995 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Forearm fracture | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fractured sacrum | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stoma complication | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ilium fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated incisional hernia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site complication | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incomplete spinal fusion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional overdose | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal anastomosis complication | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaw fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint capsule rupture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation postoperative | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint injury | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney contusion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laceration | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament sprain | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb traumatic amputation | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver contusion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes postoperative | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple fractures | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple injuries | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle strain | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patella fracture | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periprosthetic fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis chemical | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax traumatic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post laminectomy syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural bile leak | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Post procedural discharge | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematuria | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural myocardial infarction | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural swelling | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative fever | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative ileus | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative renal failure | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative respiratory failure | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative thoracic procedure complication | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound complication | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postpericardiotomy syndrome | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural complication | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural hypotension | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pneumothorax | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pubis fracture | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary contusion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius fracture | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 9 / 5992 (0.15%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 3 | |
| Scapula fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seroma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shunt malfunction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shunt occlusion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin abrasion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic rupture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Stab wound | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haematoma | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Tendon rupture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic arthritis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haematoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 5992 (0.07%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haemothorax | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic intracranial haemorrhage | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper limb fracture | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention postoperative | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm ruptured | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weaning failure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound dehiscence | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Wound haematoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Atrial septal defect | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Choledochal cyst | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Developmental hip dysplasia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal arteriovenous malformation | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocele | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic cardiomyopathy | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microgenia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute left ventricular failure | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 117 / 5992 (1.95%) | 105 / 5995 (1.75%) | |
| occurrences causally related to treatment / all | 1 / 131 | 0 / 118 | |
| deaths causally related to treatment / all | 1 / 7 | 0 / 3 | |
| Angina pectoris | | | |
| subjects affected / exposed | 123 / 5992 (2.05%) | 142 / 5995 (2.37%) | |
| occurrences causally related to treatment / all | 0 / 136 | 0 / 152 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 106 / 5992 (1.77%) | 113 / 5995 (1.88%) | |
| occurrences causally related to treatment / all | 1 / 115 | 0 / 129 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Anginal equivalent | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve disease | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve incompetence | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 4 | 2 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Arteriospasm coronary | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial fibrillation | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 102 / 5992 (1.70%) | 105 / 5995 (1.75%) | |
| occurrences causally related to treatment / all | 2 / 122 | 3 / 120 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial flutter | | | |
| subjects affected / exposed | 22 / 5992 (0.37%) | 21 / 5995 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 28 | 3 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial tachycardia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 1 / 3 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradyarrhythmia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 17 / 5992 (0.28%) | 18 / 5995 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Bundle branch block bilateral | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block left | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block right | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac aneurysm | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 19 / 5992 (0.32%) | 17 / 5995 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 11 | 0 / 11 | |
| Cardiac discomfort | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorder | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiac failure | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 21 / 5992 (0.35%) | 18 / 5995 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 25 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Cardiac failure acute | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure chronic | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 106 / 5992 (1.77%) | 91 / 5995 (1.52%) | |
| occurrences causally related to treatment / all | 2 / 139 | 3 / 124 | |
| deaths causally related to treatment / all | 1 / 3 | 0 / 1 | |
| Cardiac perforation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac tamponade | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac valve disease | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ventricular thrombosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 6 / 5992 (0.10%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 5 | 1 / 6 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 1 / 3 | 0 / 2 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Cardiovascular disorder | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cardiovascular insufficiency | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cor pulmonale | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cor pulmonale acute | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cor pulmonale chronic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 78 / 5992 (1.30%) | 87 / 5995 (1.45%) | |
| occurrences causally related to treatment / all | 0 / 80 | 3 / 92 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 8 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 8 / 5995 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery perforation | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery stenosis | | | |
| subjects affected / exposed | 13 / 5992 (0.22%) | 17 / 5995 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 13 | 1 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diastolic dysfunction | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperdynamic left ventricle | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive heart disease | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Intracardiac thrombus | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic cardiomyopathy | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kounis syndrome | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left atrial dilatation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular dysfunction | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microvascular coronary artery disease | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve disease | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 12 / 5992 (0.20%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 3 / 12 | 4 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve prolapse | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve stenosis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 31 / 5992 (0.52%) | 36 / 5995 (0.60%) | |
| occurrences causally related to treatment / all | 2 / 31 | 0 / 38 | |
| deaths causally related to treatment / all | 1 / 9 | 0 / 4 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 16 / 5992 (0.27%) | 14 / 5995 (0.23%) | |
| occurrences causally related to treatment / all | 1 / 17 | 1 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 3 | |
| Palpitations | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial cyst | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis constrictive | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary valve incompetence | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulseless electrical activity | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 1 / 1 | |
| Right ventricular failure | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 6 / 5992 (0.10%) | 15 / 5995 (0.25%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systolic dysfunction | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachycardia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 3 / 7 | 2 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular extrasystoles | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 8 / 5992 (0.13%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Ventricular tachyarrhythmia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 22 / 5992 (0.37%) | 13 / 5995 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 27 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Nervous system disorders | | | |
| Amnesia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ataxia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Balance disorder | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Basal ganglia infarction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bickerstaff's encephalitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Brain stem haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Brain stem infarction | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain stem stroke | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery disease | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 17 / 5992 (0.28%) | 15 / 5995 (0.25%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid sinus syndrome | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Central nervous system necrosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar infarction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral circulatory failure | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral infarction | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrospinal fluid leakage | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 41 / 5992 (0.68%) | 29 / 5995 (0.48%) | |
| occurrences causally related to treatment / all | 3 / 42 | 1 / 31 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Cerebrovascular disorder | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical cord compression | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical myelopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical radiculopathy | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicogenic headache | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complex partial seizures | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cranial nerve palsies multiple | | | |

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|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cubital tunnel syndrome | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Dementia Alzheimer's type | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic coma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 14 / 5995 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 9 | 2 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness postural | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolic cerebral infarction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embololic stroke | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paralysis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Frontal lobe epilepsy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Guillain-Barre syndrome | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic stroke | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Headache | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 10 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive encephalopathy | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxic-ischaemic encephalopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| IIIrd nerve paralysis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial aneurysm | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 13 / 5995 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 14 | 1 / 14 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Lacunar infarction | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar radiculopathy | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbosacral radiculopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine with aura | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Motor neurone disease | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myasthenia gravis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelomalacia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelopathy | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myoclonus | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve compression | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve root compression | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuralgia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuromyelitis optica spectrum disorder | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normal pressure hydrocephalus | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinson's disease | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinsonism | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peroneal nerve palsy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Petit mal epilepsy | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |
| subjects affected / exposed | 13 / 5992 (0.22%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radial nerve palsy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radicular pain | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Serotonin syndrome | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 4 / 4 | 3 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Simple partial seizures | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Slow speech | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal claudication | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord disorder | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitic myelopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Superficial siderosis of central nervous system | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Superior sagittal sinus thrombosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 49 / 5992 (0.82%) | 54 / 5995 (0.90%) | |
| occurrences causally related to treatment / all | 3 / 51 | 1 / 62 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Thalamus haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic encephalopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient global amnesia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 38 / 5992 (0.63%) | 46 / 5995 (0.77%) | |
| occurrences causally related to treatment / all | 0 / 39 | 3 / 55 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transverse sinus thrombosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tremor | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trigeminal neuralgia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Unresponsive to stimuli | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| With nerve paralysis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral artery dissection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral artery thrombosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar insufficiency | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord paralysis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Abdominal lymphadenopathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 19 / 5992 (0.32%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia macrocytic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Disseminated intravascular coagulation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukopenia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microcytic anaemia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normochromic normocytic anaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic haematoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spontaneous haematoma | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Tympanic membrane perforation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 8 / 5992 (0.13%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Charles Bonnet syndrome | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deformity of orbit | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular oedema | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oscillopsia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal artery occlusion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal vascular thrombosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous adhesions | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal distension | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal fat apron | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 10 / 5992 (0.17%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia obstructive | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 11 / 5992 (0.18%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 1 / 11 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fissure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal incontinence | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anorectal varices | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coeliac artery stenosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 8 / 5992 (0.13%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis microscopic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic pseudo-obstruction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 8 / 5995 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 8 / 5995 (0.13%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dieulafoy's vascular malformation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer perforation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenogastric reflux | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocoele | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erosive duodenitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erosive oesophagitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric antral vascular ectasia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric disorder | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastric perforation | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric polyps | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal angiodysplasia haemorrhagic | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 27 / 5992 (0.45%) | 29 / 5995 (0.48%) | |
| occurrences causally related to treatment / all | 0 / 30 | 0 / 29 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Gastrointestinal necrosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiatus hernia | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| 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 | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated umbilical hernia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal dilatation | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haematoma | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine polyp | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Megacolon | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric artery stenosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric panniculitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 8 / 5995 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstruction gastric | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Odynophagia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal food impaction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal pain | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal stenosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal varices haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Omental infarction | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 14 / 5992 (0.23%) | 13 / 5995 (0.22%) | |
| occurrences causally related to treatment / all | 5 / 15 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 15 / 5992 (0.25%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pancreatitis chronic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis relapsing | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 8 / 5995 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal polyp | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland mass | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 18 / 5992 (0.30%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 22 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue disorder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uvulitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visceroptosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ulcer | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Excessive skin | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity vasculitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutrophilic dermatosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Petechiae | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash erythematous | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin necrosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin ulcer | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Telangiectasia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urticaria | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 57 / 5992 (0.95%) | 57 / 5995 (0.95%) | |
| occurrences causally related to treatment / all | 1 / 64 | 0 / 61 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Acute prerenal failure | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Albuminuria | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Azotaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder disorder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder dysfunction | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neck obstruction | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder necrosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder outlet obstruction | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder prolapse | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder stenosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urinary | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic nephropathy | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End stage renal disease | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage urinary tract | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower urinary tract symptoms | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 18 / 5992 (0.30%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive uropathy | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oliguria | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proteinuria | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal artery stenosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal haemorrhage | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal infarct | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal mass | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteral disorder | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterocele | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary bladder haemorrhage | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Goitre | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperparathyroidism | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid mass | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyrotoxic crisis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | | | |
| Arthralgia | | | |
| subjects affected / exposed | 25 / 5992 (0.42%) | 25 / 5995 (0.42%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 16 / 5992 (0.27%) | 19 / 5995 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 20 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis reactive | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropathy | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 15 / 5992 (0.25%) | 16 / 5995 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical spinal stenosis | | | |
| subjects affected / exposed | 8 / 5992 (0.13%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis pyrophosphate | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exostosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibromyalgia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Flank pain | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot deformity | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture delayed union | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture malunion | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture nonunion | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gouty arthritis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemarthrosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc compression | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc displacement | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 15 / 5992 (0.25%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc space narrowing | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb discomfort | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 13 / 5992 (0.22%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mobility decreased | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monarthritis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 13 / 5992 (0.22%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myalgia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myositis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck mass | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 | 3 / 5992 (0.05%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathic arthropathy | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 109 / 5992 (1.82%) | 93 / 5995 (1.55%) | |
| occurrences causally related to treatment / all | 0 / 121 | 0 / 97 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthropathy | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteolysis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoporosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in jaw | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pathological fracture | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plantar fasciitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyarthritis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 10 / 5992 (0.17%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scoliosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue mass | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column stenosis | | | |
| subjects affected / exposed | 10 / 5992 (0.17%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal pain | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovial cyst | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral foraminal stenosis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral osteophyte | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess limb | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess neck | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess of salivary gland | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute sinusitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 9 / 5992 (0.15%) | 9 / 5995 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis perforated | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis infective | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial sepsis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 26 / 5992 (0.43%) | 18 / 5995 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Campylobacter infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Campylobacter sepsis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter site infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 71 / 5992 (1.18%) | 48 / 5995 (0.80%) | |
| occurrences causally related to treatment / all | 0 / 81 | 2 / 52 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis pasteurella | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis staphylococcal | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis streptococcal | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis infective | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic tonsillitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dengue fever | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related sepsis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gangrene | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea infectious | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 17 / 5992 (0.28%) | 23 / 5995 (0.38%) | |
| occurrences causally related to treatment / all | 0 / 22 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysematous cystitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Empyema | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia bacteraemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia infection | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia sepsis | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 13 / 5992 (0.22%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 13 | 1 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis bacterial | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis viral | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 5992 (0.05%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin infection | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| H1N1 influenza | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis A | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Human anaplasmosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Human ehrlichiosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site infection | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious colitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious pleural effusion | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Infective exacerbation of chronic obstructive airways disease | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective tenosynovitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 10 / 5992 (0.17%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney infection | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Labyrinthitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection viral | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lyme disease | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphangitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastoiditis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotising fasciitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenic sepsis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal candidiasis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 13 / 5992 (0.22%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis acute | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraspinal abscess | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirectal abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 86 / 5992 (1.44%) | 92 / 5995 (1.53%) | |
| occurrences causally related to treatment / all | 1 / 90 | 0 / 105 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia legionella | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia mycoplasmal | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia pneumococcal | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia staphylococcal | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia streptococcal | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 5992 (0.07%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural cellulitis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative abscess | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory moniliasis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rocky mountain spotted fever | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 27 / 5992 (0.45%) | 37 / 5995 (0.62%) | |
| occurrences causally related to treatment / all | 0 / 27 | 0 / 39 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 4 | |
| Sepsis syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic arthritis staphylococcal | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic embolus | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Sialoadenitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal infection | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal osteomyelitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal skin infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (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 | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth infection | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 3 / 5992 (0.05%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 40 / 5992 (0.67%) | 30 / 5995 (0.50%) | |
| occurrences causally related to treatment / all | 2 / 41 | 0 / 30 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection enterococcal | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 13 / 5995 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent infection | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular neuronitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 5992 (0.03%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulvitis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| West Nile viral infection | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 2 / 5995 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound abscess | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection pseudomonas | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection staphylococcal | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Acidosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholesterosis | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 21 / 5992 (0.35%) | 13 / 5995 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 13 / 5992 (0.22%) | 11 / 5995 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 13 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Electrolyte imbalance | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid overload | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gout | | | |
| subjects affected / exposed | 6 / 5992 (0.10%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 11 / 5992 (0.18%) | 6 / 5995 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 11 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hyperosmolar hyperglycaemic state | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperosmolar state | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperphosphataemia | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 7 / 5992 (0.12%) | 18 / 5995 (0.30%) | |
| occurrences causally related to treatment / all | 1 / 7 | 3 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 5 / 5992 (0.08%) | 10 / 5995 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 5992 (0.02%) | 4 / 5995 (0.07%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 4 / 5992 (0.07%) | 5 / 5995 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypophagia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 3 / 5995 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactic acidosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 5992 (0.02%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| 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 / 5992 (0.03%) | 0 / 5995 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obesity | | | |
| subjects affected / exposed | 12 / 5992 (0.20%) | 12 / 5995 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 11 / 5992 (0.18%) | 7 / 5995 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 5992 (0.00%) | 1 / 5995 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Placebo | Lorcaserin 10 mg | |
|---|----------------------|----------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4788 / 5992 (79.91%) | 4946 / 5995 (82.50%) | |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 340 / 5992 (5.67%) | 537 / 5995 (8.96%) | |
| occurrences (all) | 407 | 640 | |
| Headache | | | |

| | | | |
|---|---------------------------|---------------------------|--|
| subjects affected / exposed occurrences (all) | 274 / 5992 (4.57%) 316 | 383 / 5995 (6.39%) 445 | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 302 / 5992 (5.04%) | 496 / 5995 (8.27%) | |
| occurrences (all) | 329 | 548 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 340 / 5992 (5.67%) | 267 / 5995 (4.45%) | |
| occurrences (all) | 385 | 294 | |
| Gastrointestinal disorders | | | |
| Constipation | | | |
| subjects affected / exposed | 248 / 5992 (4.14%) | 336 / 5995 (5.60%) | |
| occurrences (all) | 268 | 362 | |
| Diarrhoea | | | |
| subjects affected / exposed | 324 / 5992 (5.41%) | 419 / 5995 (6.99%) | |
| occurrences (all) | 362 | 478 | |
| Nausea | | | |
| subjects affected / exposed | 286 / 5992 (4.77%) | 356 / 5995 (5.94%) | |
| occurrences (all) | 329 | 398 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 303 / 5992 (5.06%) | 376 / 5995 (6.27%) | |
| occurrences (all) | 351 | 431 | |
| Dyspnoea | | | |
| subjects affected / exposed | 310 / 5992 (5.17%) | 285 / 5995 (4.75%) | |
| occurrences (all) | 347 | 312 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 452 / 5992 (7.54%) | 457 / 5995 (7.62%) | |
| occurrences (all) | 542 | 544 | |
| Back pain | | | |
| subjects affected / exposed | 452 / 5992 (7.54%) | 457 / 5995 (7.62%) | |
| occurrences (all) | 496 | 496 | |
| Infections and infestations | | | |

| | | | |
|-----------------------------------|--------------------|--------------------|--|
| Bronchitis | | | |
| subjects affected / exposed | 468 / 5992 (7.81%) | 455 / 5995 (7.59%) | |
| occurrences (all) | 584 | 536 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 338 / 5992 (5.64%) | 353 / 5995 (5.89%) | |
| occurrences (all) | 418 | 426 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 567 / 5992 (9.46%) | 528 / 5995 (8.81%) | |
| occurrences (all) | 690 | 659 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 400 / 5992 (6.68%) | 440 / 5995 (7.34%) | |
| occurrences (all) | 575 | 593 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|----------------|--|
| 06 August 2015 | Amendment 01: The secondary objective related to glycemic control was reclassified. The exploratory objective was added. Instructions that the first dose should be taken at Visit 2. Inclusion and exclusion criteria's were updated. Renal impairment: defined with reference to estimated glomerular filtration rate rather than clearance. Cyproheptadine, amoxapine, tricyclic antidepressants, and mirtazapine was deleted from the list of drugs increasing the risk for cardiac valvulopathy/PH. List of prohibited drugs was revised and the restrictions on serotonergic drugs was clarified. An analysis of subjects having worsened valvulopathy at 1 year and yearly and had FDA-defined valvulopathy at Baseline was added as a secondary endpoint. Study population for conversion to diabetes was changed to prediabetes population. Confirmatory test was needed for subjects with new onset of diabetes. Dosing instructions was modified. It was clarified that nicotine use was not exclusionary. Hospitalizations for administration of study drug or insertion of access for administration of study drug was removed from the list of hospitalization that are not SAEs because it was not applicable to the study. Clarification on subjects who permanently discontinued study drug were to complete the EOT visit within 30 days. Euphoria and suicidal ideation was moved from study-specific AEs of interest to 'SAEs and Events Associated with Special Situations'. It was added that renal function parameters and glycemic profile should be collected at all visits. It was specified that SAE collection for 30 days after the last drug dose applied only to subjects taking study drug at the time of study completion, since some subjects may have discontinued study drug before study completion. Revised footnote b in Schedule of Procedures/Assessments pertaining to unscheduled visits for assessments required by state-controlled substance requirements. |
| 30 March 2017 | Amendment 02: The primary objective of conversion to T2DM was changed to a secondary objective because the timelines to demonstrate the primary endpoint for conversion to Type 2 diabetes were not as initially projected, due to the low rate of conversion, Removed HbA1c from the exploratory objective in order to have a broader assessment of glycemic benefit in subjects with diabetes, Added FPG, fasting insulin levels, and homeostatic model assessment-insulin resistance (HOMA-IR) to better assess lorcaserin glycemic benefit, Multiple testing procedure was updated to reflect the change in the primary objective, The renal objective for the overall population was added and reorganized for clarification, Details of the interim analysis was outlined in the Study Integrity Charter, Removed the clarification of major adverse cardiovascular events (MACE)+ events accruing after 11 months after 460 MACE events have occurred, Updated the timing of the interim analysis date. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported