



Clinical trial results:

A Randomized, Double-blind, Event-driven, Multicenter Study Comparing the Efficacy and Safety of Rivaroxaban with Placebo for Reducing the Risk of Death, Myocardial Infarction or Stroke in Subjects with Heart Failure and Significant Coronary Artery Disease Following an Episode of Decompensated Heart Failure

Summary

| | |
|--------------------------|--|
| EudraCT number | 2013-000046-19 |
| Trial protocol | ES CZ DE NL BG PL HU SE IT GB EE LT PT DK LV SK GR |
| Global end of trial date | 02 May 2018 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 04 May 2019 |
| First version publication date | 04 May 2019 |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | RIVAROXHFA3001 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01877915 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Janssen Research & Development, LLC |
| Sponsor organisation address | 920, Route 202 South, Raritan, NJ, United States, 08869 |
| Public contact | Clinical Registry group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com |
| Scientific contact | Clinical Registry group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.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 | 02 May 2018 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|-------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 02 May 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to demonstrate that rivaroxaban was superior to placebo in subjects with heart failure (HF) and significant coronary artery disease (CAD), who were receiving standard care, in reducing the risk of the composite of all-cause mortality (ACM), myocardial infarction (MI), or stroke following an index event.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices (GCP) and applicable regulatory requirements. Safety was assessed by the evaluation of the principal safety outcome, other bleeding outcomes, Adverse Events and laboratory evaluations.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 06 September 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Argentina: 152 |
| Country: Number of subjects enrolled | Australia: 14 |
| Country: Number of subjects enrolled | Bulgaria: 628 |
| Country: Number of subjects enrolled | Brazil: 160 |
| Country: Number of subjects enrolled | Canada: 28 |
| Country: Number of subjects enrolled | China: 372 |
| Country: Number of subjects enrolled | Czech Republic: 69 |
| Country: Number of subjects enrolled | Germany: 64 |
| Country: Number of subjects enrolled | Denmark: 18 |
| Country: Number of subjects enrolled | Spain: 178 |
| Country: Number of subjects enrolled | France: 20 |
| Country: Number of subjects enrolled | United Kingdom: 25 |
| Country: Number of subjects enrolled | Greece: 16 |
| Country: Number of subjects enrolled | Hungary: 138 |
| Country: Number of subjects enrolled | Italy: 71 |
| Country: Number of subjects enrolled | Japan: 265 |
| Country: Number of subjects enrolled | Korea, Republic of: 48 |
| Country: Number of subjects enrolled | Lithuania: 35 |

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Latvia: 25 |
| Country: Number of subjects enrolled | Mexico: 146 |
| Country: Number of subjects enrolled | Malaysia: 34 |
| Country: Number of subjects enrolled | Netherlands: 3 |
| Country: Number of subjects enrolled | Poland: 578 |
| Country: Number of subjects enrolled | Portugal: 42 |
| Country: Number of subjects enrolled | Romania: 398 |
| Country: Number of subjects enrolled | Russian Federation: 550 |
| Country: Number of subjects enrolled | Slovakia: 82 |
| Country: Number of subjects enrolled | Sweden: 5 |
| Country: Number of subjects enrolled | Turkey: 192 |
| Country: Number of subjects enrolled | Ukraine: 529 |
| Country: Number of subjects enrolled | United States: 121 |
| Country: Number of subjects enrolled | South Africa: 16 |
| Worldwide total number of subjects | 5022 |
| EEA total number of subjects | 2395 |

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) | 2159 |
| From 65 to 84 years | 2709 |
| 85 years and over | 154 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 5,667 subjects were screened for eligibility and 5,022 subjects were randomly assigned into 1 of the 2 treatment groups: rivaroxaban (N= 2,507) or matching placebo (N=2,515).

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 | Investigator, Subject |

Arms

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

Arm description:

Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Rivaroxaban 2.5 mg |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects received 2.5 mg of rivaroxaban tablet orally twice daily.

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

Arm description:

Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

| | |
|--|----------|
| 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:

Subjects received matching placebo orally twice daily.

| Number of subjects in period 1 | Rivaroxaban | Placebo |
|---------------------------------------|-------------|---------|
| Started | 2507 | 2515 |
| Completed | 2453 | 2447 |
| Not completed | 54 | 68 |
| Consent withdrawn by subject | 42 | 55 |
| Other | 2 | 4 |
| Lost to follow-up | 10 | 9 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Rivaroxaban |
|-----------------------|-------------|

Reporting group description:

Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

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

Reporting group description:

Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

| Reporting group values | Rivaroxaban | Placebo | Total |
|---|-------------|---------|-------|
| Number of subjects | 2507 | 2515 | 5022 |
| Title for AgeCategorical Units: subjects | | | |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 1061 | 1098 | 2159 |
| From 65 to 84 years | 1379 | 1330 | 2709 |
| 85 years and over | 67 | 87 | 154 |
| Title for AgeContinuous Units: years | | | |
| arithmetic mean | 66.5 | 66.3 | |
| standard deviation | ± 10.07 | ± 10.27 | - |
| Title for Gender Units: subjects | | | |
| Female | 551 | 599 | 1150 |
| Male | 1956 | 1916 | 3872 |

End points

End points reporting groups

| | |
|--|-------------|
| Reporting group title | Rivaroxaban |
| Reporting group description: Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician). | |
| Reporting group title | Placebo |
| Reporting group description: Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician). | |

Primary: Event Rate of All-Cause Mortality, Myocardial Infarction (MI), or Stroke

| | |
|--|--|
| End point title | Event Rate of All-Cause Mortality, Myocardial Infarction (MI), or Stroke |
| End point description: Event rate of all-cause mortality (ACM), MI, or stroke were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. Intent-to-Treat (ITT) analysis set included all randomized unique subjects who signed a valid informed consent. Subjects were analyzed according to the treatment group assigned, irrespective of the actual treatment received. | |
| End point type | Primary |
| End point timeframe: Up to Global treatment end date (approximately 54 months) | |

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2507 | 2515 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 13.44 | 14.27 | | |

Statistical analyses

| | |
|---|------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Rivaroxaban v Placebo |
| Number of subjects included in analysis | 5022 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.27 |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.94 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.05 |

Primary: Event Rate of Either Fatal Bleeding or Bleeding into a Critical Space with Potential for Permanent Disability

| | |
|-----------------|---|
| End point title | Event Rate of Either Fatal Bleeding or Bleeding into a Critical Space with Potential for Permanent Disability |
|-----------------|---|

End point description:

Event rate of either fatal bleeding or bleeding into critical space with potential for permanent disability were assessed. Fatal bleeding event was death within 7 days after bleeding event which required hospitalization or met ISTH major bleeding definition criteria. Fatal bleeding event included that met criteria in 3 1: Any ISTH major bleeding event considered to be primary cause of death by investigator; 2: ISTH major bleeding event not considered primary cause of death by investigator but resulted in death within 7 days; 3: Any bleeding event resulted in hospital and death within 7 days. Bleeding with potential for permanent disability included 7 critical spaces: intracranial, intraspinal, intraocular. Event rate based on time to first occurrence of event were reported in the study. Event Rate/(100 pt-yr)=100*n/(total risk exposure), where n is number of events. SAS: subjects who received at least one dose of study drug. 'N': number of subjects evaluable for this outcome measure.

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

End point timeframe:

Up to 227 Weeks

| End point values | Rivaroxaban | Placebo | | |
|---|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2499 | 2509 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | | | | |
| Fatal Bleeding | 0.22 | 0.22 | | |
| Critical Space Bleeding with Permanent Disability | 0.32 | 0.48 | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 1 (Fatal Bleeding) |
| Comparison groups | Rivaroxaban v Placebo |
| Number of subjects included in analysis | 5008 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.951 |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.03 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.41 |
| upper limit | 2.59 |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 (Permanent Disability) |
| Comparison groups | Rivaroxaban v Placebo |
| Number of subjects included in analysis | 5008 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.253 |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.67 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.33 |
| upper limit | 1.34 |

Secondary: Event Rate of Cardio Vascular Death or Re-Hospitalization for Worsening of Heart Failure (RHHF)

| | |
|--|---|
| End point title | Event Rate of Cardio Vascular Death or Re-Hospitalization for Worsening of Heart Failure (RHHF) |
| End point description: | |
| Event rate of cardio vascular (CV) death or re-hospitalization for worsening of heart failure were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Global treatment end date (approximately 54 months) | |

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2507 | 2515 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 23.32 | 23.46 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Cardio Vascular Death

| | |
|---|-------------------------------------|
| End point title | Event Rate of Cardio Vascular Death |
| End point description: Event rate of cardio vascular death were assessed. CV death included deaths due to spontaneous bleeding, MI, stroke, worsening HF and arrhythmias, death due to CV procedures and sudden death. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. IIT analysis set included all randomized unique subjects signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received. | |
| End point type | Secondary |
| End point timeframe: Up to Global treatment end date (approximately 54 months) | |

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2507 | 2515 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 9.46 | 9.96 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Re-Hospitalization for Worsening of Heart Failure

| | |
|--|---|
| End point title | Event Rate of Re-Hospitalization for Worsening of Heart Failure |
| End point description: Event rate of re-hospitalization for worsening of heart failure were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received. | |
| End point type | Secondary |
| End point timeframe: Up to Global treatment end date (approximately 54 months) | |

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2507 | 2515 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 17.24 | 17.45 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Re-Hospitalization for Cardio Vascular Events (RHCV)

| | |
|-----------------|--|
| End point title | Event Rate of Re-Hospitalization for Cardio Vascular Events (RHCV) |
|-----------------|--|

End point description:

Event rate of RHCV were assessed. Hospitalization for a CV event required that participants be hospitalized (in-patient or emergency department) for greater than 24 hours and must have met the following criterion: Discharge summary with primary reason for admission listed as CV in nature (eg, bleeding, arrhythmia, ACS, MI) other than HF which was captured in HF re-hospitalization. Event rate estimated based on time to first occurrence of the event were reported in study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received.

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

End point timeframe:

Up to Global treatment end date (approximately 54 months)

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2507 | 2515 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 13.30 | 14.04 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of all-Cause Mortality (ACM) or Re-Hospitalization for Worsening Heart Failure

| | |
|-----------------|---|
| End point title | Event Rate of all-Cause Mortality (ACM) or Re-Hospitalization for Worsening Heart Failure |
|-----------------|---|

End point description:

Event rate of all-cause mortality (ACM) or re-hospitalization for worsening heart failure were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. IIT analysis set included all randomized unique subjects who signed a valid informed consent. Subjects analyzed according to treatment group assigned, irrespective of actual treatment received.

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

End point timeframe:

Up to Global treatment end date (approximately 54 months)

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2507 | 2515 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 24.84 | 24.57 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of Bleeding Events that Requiring Hospitalization

| | |
|--|--|
| End point title | Event Rate of Bleeding Events that Requiring Hospitalization |
| End point description: | |
| Event rate of bleeding events and required Hospitalization were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. Safety Analysis Set (SAS) included all intent-to-treat subjects who received at least one dose of study drug. Here 'N' signifies number of subjects who were evaluable for this outcome measure. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 227 Weeks | |

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2499 | 2509 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 1.52 | 1.16 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Event Rate of International Society on Thrombosis and Haemostasis (ISTH) Major Bleeding Event

| | |
|---|---|
| End point title | Event Rate of International Society on Thrombosis and Haemostasis (ISTH) Major Bleeding Event |
| End point description: | |
| Event rate of ISTH major bleeding event were assessed. Event rate estimated based on the time to the first occurrence of the event were reported in the study. Event Rate / (100 pt-yr) = $100 \times n / (\text{total risk exposure})$, where n is the number of events. Safety Analysis Set included all intent-to-treat subjects who received at least one dose of study drug. Here 'N' signifies number of subjects who were evaluable for this outcome measure. | |

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to 227 Weeks | |

| End point values | Rivaroxaban | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2499 | 2509 | | |
| Units: Event rate per 100 patient-year | | | | |
| number (not applicable) | 2.04 | 1.21 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 54 Months

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 20.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | Rivaroxaban |
|-----------------------|-------------|

Reporting group description:

Subjects received 2.5 milligram (mg) tablet of rivaroxaban orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

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

Reporting group description:

Subjects received matching placebo orally twice daily with standard of care for heart failure and coronary artery disease (as prescribed by the subject's managing physician).

| Serious adverse events | Rivaroxaban | Placebo | |
|---|------------------------|------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 479 / 2507 (19.11%) | 451 / 2515 (17.93%) | |
| number of deaths (all causes) | 565 | 571 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute Myeloid Leukaemia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of Colon | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder Cancer | | | |
| subjects affected / exposed | 6 / 2507 (0.24%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Bladder Cancer Recurrent | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain Neoplasm | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Cancer Stage Ii | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Neoplasm | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Bronchial Carcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Cervix Carcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Lymphocytic Leukaemia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clear Cell Renal Cell Carcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Colon Cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 7 / 2507 (0.28%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 2 / 2 | 1 / 1 | |
| Colon Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Colon Cancer Recurrent | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal Adenocarcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal Cancer | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear Neoplasm Malignant | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Epiglottic Carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder Cancer | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Gastric Cancer | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric Cancer Recurrent | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal Cancer | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hepatic Cancer | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic Cancer Stage Iv | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Hypopharyngeal Cancer | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Intestinal Adenocarcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Lung Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 1 / 1 | 1 / 1 | |
| Lung Carcinoma Cell Type Unspecified Stage Ii | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Lung Neoplasm | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Lung Neoplasm Malignant | | | |
| subjects affected / exposed | 7 / 2507 (0.28%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 7 | |
| deaths causally related to treatment / all | 5 / 5 | 1 / 1 | |
| Lymphoma | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Malignant Melanoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Meningioma | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to Bone | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to Central Nervous System | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Metastases to Liver | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Metastases to Lung | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic Neoplasm | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Metastatic Renal Cell Carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Monoclonal Gammopathy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm Malignant | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Neoplasm of Orbit | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Hodgkin's Lymphoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal Adenocarcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal Squamous Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic Carcinoma | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Pancreatic Carcinoma Metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 2 / 2 | |
| Plasma Cell Myeloma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Prostate Cancer | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Prostate Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate Cancer Stage Iv | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal Adenocarcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal Cancer Stage Iii | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Rectal Neoplasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 2 / 2507 (0.08%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Renal Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Neoplasm | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small Cell Carcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small Intestine Carcinoma | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Squamous Cell Carcinoma | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Testis Cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Throat Cancer | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid Cancer | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Tongue Neoplasm | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue Neoplasm Malignant Stage Unspecified | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Aortic Aneurysm | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic Dissection | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial Haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 1 / 1 | |
| Cryoglobulinaemia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Vascular Disorder | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity Necrosis | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemic Shock | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic Hypotension | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Arterial Occlusive Disease | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Ischaemia | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Vascular Disorder | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phlebitis Superficial | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian Artery Stenosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Anal Sphincterotomy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile Duct Stent Removal | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Tumour Excision | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract Operation | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chemotherapy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyst Removal | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Debridement | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes Mellitus Management | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug Therapy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia Repair | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileostomy | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal Hernia Repair | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Insertion of Ambulatory Peritoneal Catheter | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leg Amputation | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Artery Bypass | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prosthetic Vessel Implantation | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Removal of Ambulatory Peritoneal Catheter | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal Fusion Surgery | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal Laminectomy | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transurethral Prostatectomy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 2 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Chest Discomfort | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 3 / 3 | |
| Disuse Syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Drug Withdrawal Syndrome | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General Physical Health Deterioration | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Heteroplasia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthermia Malignant | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple Organ Dysfunction Syndrome | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 5 / 5 | 3 / 3 | |
| Non-Cardiac Chest Pain | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 7 / 2507 (0.28%) | 6 / 2515 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft Tissue Inflammation | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden Death | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoidosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Benign Prostatic Hyperplasia | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|------------------|------------------|--|
| Cystocele | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gynaecomastia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian Cyst Torsion | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute Pulmonary Oedema | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Respiratory Failure | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Asthma | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |

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|---|-------------------|-------------------|--|
| Atelectasis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiectasis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis Chronic | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Obstructive Pulmonary Disease | | | |
| subjects affected / exposed | 15 / 2507 (0.60%) | 16 / 2515 (0.64%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 21 | |
| deaths causally related to treatment / all | 1 / 1 | 1 / 1 | |
| Cough | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea Paroxysmal Nocturnal | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysema | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Disorder | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Infiltration | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotising Bronchiolitis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Pleural Effusion | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleurisy | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia Aspiration | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 2507 (0.16%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 1 / 1 | |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Fibrosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Hypertension | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Mass | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Oedema | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory Arrest | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Respiratory Failure | | | |
| subjects affected / exposed | 9 / 2507 (0.36%) | 5 / 2515 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 5 | |
| deaths causally related to treatment / all | 4 / 4 | 3 / 3 | |
| Respiratory Tract Inflammation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep Apnoea Syndrome | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal Cord Thickening | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Alcohol Abuse | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol Withdrawal Syndrome | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholism | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Antisocial Personality Disorder | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety Disorder | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional State | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Illness Anxiety Disorder | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Major Depression | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic Disorder Due to A General Medical Condition | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Self-Injurious Ideation | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide Attempt | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device Dislocation | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Acute Hepatic Failure | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile Duct Stone | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary Colic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary Dilatation | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac Cirrhosis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Cholangitis Acute | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 10 / 2507 (0.40%) | 5 / 2515 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis Acute | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis Chronic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cirrhosis Alcoholic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hepatic Cirrhosis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic Failure | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hepatic Function Abnormal | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic Lesion | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis Acute | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatorenal Failure | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Jaundice | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver Disorder | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal Hypertension | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Biopsy Pleura | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biopsy Prostate | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood Creatine Phosphokinase Increased | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood Glucose Abnormal | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood Glucose Fluctuation | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic Enzyme Increased | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver Function Test Increased | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagogastroduodenoscopy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Platelet Count Decreased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol Poisoning | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Ankle Fracture | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone Fissure | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns Third Degree | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral Injury | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Fall | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Femoral Neck Fracture | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur Fracture | | | |
| subjects affected / exposed | 8 / 2507 (0.32%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign Body | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gun Shot Wound | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Hand Fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head Injury | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hip Fracture | | | |
| subjects affected / exposed | 6 / 2507 (0.24%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional Overdose | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb Injury | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower Limb Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patella Fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax Traumatic | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative Renal Failure | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiation Pneumonitis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib Fracture | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road Traffic Accident | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 2507 (0.12%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 1 / 1 | 1 / 1 | |
| Spinal Compression Fracture | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon Rupture | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal Burn | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulna Fracture | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound Dehiscence | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | | | |
| Arteriovenous Malformation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Buried Penis Syndrome | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocele | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac Failure | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiogenic Shock | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiorenal Syndrome | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocarditis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Palpitations | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Amyotrophic Lateral Sclerosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Brain Injury | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Brain Oedema | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Carpal Tunnel Syndrome | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicobrachial Syndrome | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Neuropathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness Postural | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemianopia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic Coma | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxic-Ischaemic Encephalopathy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Intercostal Neuralgia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic Neuropathy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of Consciousness | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbosacral Radiculopathy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic Encephalopathy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroglycopenia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 6 / 2507 (0.24%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 12 / 2507 (0.48%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 4 / 13 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia Vitamin B12 Deficiency | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aplastic Anaemia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disseminated Intravascular Coagulation | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron Deficiency Anaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Vertigo | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo Positional | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 7 / 2507 (0.28%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract Nuclear | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Retinopathy | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular Hole | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmoplegia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal Detachment | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinopathy Hypertensive | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subretinal Fibrosis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual Acuity Reduced | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal Pain | | | |
| subjects affected / exposed | 6 / 2507 (0.24%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal Pain Upper | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal Tenderness | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Gastritis | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coeliac Disease | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dental Caries | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Diverticulum Intestinal | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal Obstruction | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erosive Duodenitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food Poisoning | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis Erosive | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal Angiodysplasia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal Disorder | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal Necrosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal Reflux Disease | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 2507 (0.12%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal Sphincter Insufficiency | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernial Eventration | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus Paralytic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Incarcerated Inguinal Hernia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated Umbilical Hernia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory Bowel Disease | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal Hernia | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 7 / 2507 (0.28%) | 9 / 2515 (0.36%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal Infarction | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Intestinal Obstruction | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic Enteritis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large Intestinal Obstruction | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Large Intestine Polyp | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic Disorder | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic Necrosis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis Acute | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis Chronic | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subileus | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulcerative Gastritis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Volvulus of Small Bowel | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus Ulcer | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Foot | | | |
| subjects affected / exposed | 6 / 2507 (0.24%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyshidrotic Eczema | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity Vasculitis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrobiosis Lipoidica Diabeticorum | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash Generalised | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash Macular | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin Lesion | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic Epidermal Necrolysis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute Kidney Injury | | | |
| subjects affected / exposed | 17 / 2507 (0.68%) | 28 / 2515 (1.11%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 33 | |
| deaths causally related to treatment / all | 3 / 3 | 2 / 2 | |
| Calculus Urinary | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Kidney Disease | | | |
| subjects affected / exposed | 14 / 2507 (0.56%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 7 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Diabetic Nephropathy | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End Stage Renal Disease | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iga Nephropathy | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy Toxic | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrotic Syndrome | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prerenal Failure | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Artery Stenosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Colic | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Failure | | | |
| subjects affected / exposed | 12 / 2507 (0.48%) | 12 / 2515 (0.48%) | |
| occurrences causally related to treatment / all | 1 / 14 | 0 / 13 | |
| deaths causally related to treatment / all | 2 / 2 | 3 / 3 | |
| Renal Impairment | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 9 / 2515 (0.36%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral Stenosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Retention | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Tract Disorder | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Tract Obstruction | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Basedow's Disease | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back Pain | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot Deformity | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral Disc Degeneration | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral Disc Disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar Spinal Stenosis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular Weakness | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal Chest Pain | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondrosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in Extremity | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia Rheumatica | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid Arthritis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal Osteoarthritis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal Pain | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal Abscess | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess Limb | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess Soft Tissue | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal Abscess | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis Bacterial | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial Infection | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 12 / 2507 (0.48%) | 9 / 2515 (0.36%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis Bacterial | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis Infective | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbuncle | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 7 / 2507 (0.28%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis Gangrenous | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Cholecystitis Infective | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Tonsillitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium Difficile Colitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dengue Fever | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Foot Infection | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Gangrene | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Douglas' Abscess | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis Infectious | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterobacter Infection | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia Bacteraemia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia Infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia Pyelonephritis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia Sepsis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia Urinary Tract Infection | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 7 / 2507 (0.28%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 2 / 2 | 0 / 0 | |
| Gastritis Viral | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 6 / 2507 (0.24%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Shigella | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Viral | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic Pneumonia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Hepatitis E | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes Zoster Infection Neurological | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected Dermal Cyst | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected Skin Ulcer | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective Spondylitis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 7 / 2507 (0.28%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Intervertebral Discitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 | 3 / 2507 (0.12%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower Respiratory Tract Infection | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Abscess | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Infection | | | |
| subjects affected / exposed | 8 / 2507 (0.32%) | 6 / 2515 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical Device Site Infection | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Myiasis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Pancreas Infection | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Parotid Abscess | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periodontitis | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 1 / 1 | 2 / 2 | |
| Pharyngeal Abscess | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 68 / 2507 (2.71%) | 72 / 2515 (2.86%) | |
| occurrences causally related to treatment / all | 0 / 80 | 0 / 78 | |
| deaths causally related to treatment / all | 9 / 9 | 13 / 13 | |
| Pneumonia Bacterial | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 5 / 2515 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 2 / 2 | |
| Pneumonia Klebsiella | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia Staphylococcal | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (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 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Postoperative Wound Infection | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Tuberculosis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 2507 (0.08%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis Acute | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 2 / 2 | |
| Pyuria | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory Tract Infection | | | |
| subjects affected / exposed | 10 / 2507 (0.40%) | 8 / 2515 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 9 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 16 / 2507 (0.64%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 7 | |
| deaths causally related to treatment / all | 7 / 7 | 2 / 2 | |
| Septic Shock | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 6 / 2515 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 2 / 2 | 3 / 3 | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| 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 | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syphilis | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheitis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 14 / 2507 (0.56%) | 9 / 2515 (0.36%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Urinary Tract Infection Bacterial | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral Myocarditis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound Infection | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 1 / 1 | 1 / 1 | |
| Metabolism and nutrition disorders | | | |
| Acidosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cachexia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Decreased Appetite | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 2 / 2515 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 7 / 2507 (0.28%) | 8 / 2515 (0.32%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes Mellitus Inadequate Control | | | |
| subjects affected / exposed | 9 / 2507 (0.36%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Ketosis | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Metabolic Decompensation | | | |
| subjects affected / exposed | 2 / 2507 (0.08%) | 4 / 2515 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte Imbalance | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid Retention | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 3 / 2507 (0.12%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemic Hyperosmolar Nonketotic Syndrome | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 4 / 2507 (0.16%) | 7 / 2515 (0.28%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hypervolaemia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 5 / 2515 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 5 / 2515 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Insulin-Requiring Type 2 Diabetes Mellitus | | | |
| subjects affected / exposed | 0 / 2507 (0.00%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactic Acidosis | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic Disorder | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 1 / 2515 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 1 Diabetes Mellitus | | | |
| subjects affected / exposed | 1 / 2507 (0.04%) | 0 / 2515 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 Diabetes Mellitus | | | |
| subjects affected / exposed | 5 / 2507 (0.20%) | 3 / 2515 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Rivaroxaban | Placebo | |
|---|-------------------|-------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 53 / 2507 (2.11%) | 60 / 2515 (2.39%) | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 53 / 2507 (2.11%) | 60 / 2515 (2.39%) | |
| occurrences (all) | 80 | 77 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported