



Clinical trial results:

A trial comparing cardiovascular safety of insulin degludec versus insulin glargine in subjects with type 2 diabetes at high risk of cardiovascular events

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2013-002371-17 |
| Trial protocol | GB PL GR IT ES HR |
| Global end of trial date | 16 October 2016 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 02 November 2017 |
| First version publication date | 02 November 2017 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | EX1250-4080 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01959529 |
| WHO universal trial number (UTN) | U1111-1141-7614 |
| Other trial identifiers | Japanese trial registration number: JapicCTI-142464, CTN: 25-3375 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Novo Nordisk A/S |
| Sponsor organisation address | Novo Allé, Bagsvaerd, Denmark, 2880 |
| Public contact | Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com |
| Scientific contact | Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 24 March 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 16 October 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 October 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to confirm the cardiovascular safety of insulin degludec (IDeg) compared to that of insulin glargine (IGlar).

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki Amended 2013 and ICH Good Clinical Practice (1996) and with FDA 21 CFR 312.120 in the United States.

Background therapy:

Subjects continued their pre-trial medication except for the basal insulin, which was replaced by any of the investigational medicinal products (IMPs; IDeg or IGlar). The pre-trial bolus insulin was allowed and could be replaced with insulin aspart (IAsp) at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg once daily (OD)/IGlar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin twice daily (BID), the total basal component was calculated, reduced by 20-30% and switched to IDeg OD/ IGlar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 29 October 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: 120 |
| Country: Number of subjects enrolled | Brazil: 303 |
| Country: Number of subjects enrolled | Canada: 70 |
| Country: Number of subjects enrolled | Algeria: 63 |
| Country: Number of subjects enrolled | Spain: 60 |
| Country: Number of subjects enrolled | United Kingdom: 80 |
| Country: Number of subjects enrolled | Greece: 90 |
| Country: Number of subjects enrolled | Croatia: 46 |
| Country: Number of subjects enrolled | India: 357 |
| Country: Number of subjects enrolled | Italy: 140 |
| Country: Number of subjects enrolled | Japan: 61 |
| Country: Number of subjects enrolled | Korea, Republic of: 61 |
| Country: Number of subjects enrolled | Mexico: 162 |
| Country: Number of subjects enrolled | Malaysia: 102 |
| Country: Number of subjects enrolled | Poland: 135 |

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Romania: 84 |
| Country: Number of subjects enrolled | Russian Federation: 240 |
| Country: Number of subjects enrolled | Thailand: 68 |
| Country: Number of subjects enrolled | United States: 5201 |
| Country: Number of subjects enrolled | South Africa: 194 |
| Worldwide total number of subjects | 7637 |
| EEA total number of subjects | 635 |

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) | 3682 |
| From 65 to 84 years | 3917 |
| 85 years and over | 38 |

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 438 sites in 20 countries as follows: Algeria: 6; Argentina: 4; Brazil: 10; Canada: 6; Croatia: 5; Greece: 6; India: 26; Italy: 10; Japan: 8; Republic of Korea: 4; Malaysia: 8; Mexico: 7; Poland: 8; Romania: 4; Russian Federation: 20; South Africa: 15; Spain: 6; Thailand: 6; United Kingdom: 8; United States: 271.

Pre-assignment

Screening details:

Not applicable

Period 1

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

Blinding implementation details:

The trial was double-blinded and subjects were randomised 1:1 to receive IDeg or IGLar. Both treatments were provided in identical 10 mL blinded vials.

Arms

| | |
|------------------------------|------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Insulin degludec |

Arm description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Insulin degludec |
| Investigational medicinal product code | |
| Other name | Tresiba® |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

IDeg 100 units/mL OD was self administered by subjects S.C. in thigh, upper arm or the abdominal wall between dinner and bedtime.

| | |
|------------------|------------------|
| Arm title | Insulin glargine |
|------------------|------------------|

Arm description:

Subjects received IGLar 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pretrial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGLar). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGLar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGLar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

| | |
|----------|-------------------|
| Arm type | Active comparator |
|----------|-------------------|

| | |
|--|------------------------|
| Investigational medicinal product name | Insulin glargine |
| Investigational medicinal product code | |
| Other name | Lantus® |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

IGlar 100 units/mL OD was self administered by subjects S.C. in thigh, upper arm or the abdominal wall between dinner and bedtime.

| Number of subjects in period 1 | Insulin degludec | Insulin glargine |
|---------------------------------------|------------------|------------------|
| Started | 3818 | 3819 |
| Exposed | 3809 | 3806 |
| Completed | 3742 | 3747 |
| Not completed | 76 | 72 |
| Adverse event (not hypoglycaemia) | - | 1 |
| Lack of glycaemic control | 1 | 1 |
| Unspecified | 70 | 68 |
| Lost to follow-up | 4 | 1 |
| Hypoglycaemia | 1 | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|------------------|
| Reporting group title | Insulin degludec |
|-----------------------|------------------|

Reporting group description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

| | |
|-----------------------|------------------|
| Reporting group title | Insulin glargine |
|-----------------------|------------------|

Reporting group description:

Subjects received IGl 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGl). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGl OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGl OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

| Reporting group values | Insulin degludec | Insulin glargine | Total |
|---------------------------------------|------------------|------------------|-------|
| Number of subjects | 3818 | 3819 | 7637 |
| Age Categorical Units: Subjects | | | |
| Adults (18-64 years) | 1835 | 1847 | 3682 |
| From 65-84 years | 1969 | 1948 | 3917 |
| 85 years and over | 14 | 24 | 38 |
| Age Continuous Units: years | | | |
| arithmetic mean | 64.9 | 65.0 | |
| standard deviation | ± 7.3 | ± 7.5 | - |
| Gender Categorical Units: Subjects | | | |
| Female | 1422 | 1437 | 2859 |
| Male | 2396 | 2382 | 4778 |
| HbA1c Units: percentage of HbA1c | | | |
| arithmetic mean | 8.44 | 8.41 | |
| standard deviation | ± 1.63 | ± 1.67 | - |

End points

End points reporting groups

| | |
|-----------------------|------------------|
| Reporting group title | Insulin degludec |
|-----------------------|------------------|

Reporting group description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

| | |
|-----------------------|------------------|
| Reporting group title | Insulin glargine |
|-----------------------|------------------|

Reporting group description:

Subjects received IGlar 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pretrial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGlar). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGlar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGlar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

Primary: Time from randomisation to first occurrence of a major adverse cardiovascular event (MACE): cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke.

| | |
|-----------------|---|
| End point title | Time from randomisation to first occurrence of a major adverse cardiovascular event (MACE): cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke. |
|-----------------|---|

End point description:

Time from randomisation to first occurrence of an EAC-confirmed 3-component major adverse cardiovascular event (MACE): cardiovascular death, non-fatal myocardial infarction, or nonfatal stroke. Events with event adjudication committee (EAC)-confirmed onset date between randomisation and individual end of trial were included in the analyses. The number of subjects experiencing first EAC-confirmed MACE, date between randomisation to the end of trial, both days included were presented. The trial was event driven and planned to last up to a maximum of 60.5 months. The actual trial duration (time from first subject first visit to last subject last visit) was 35.6 months. The maximum trial duration for a single subject was 33.1 months. The analysis was based on the FAS, which included all randomised subjects.

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

End point timeframe:

From randomisation to individual end of trial date (maximum patient year observation: 2.75 years)

| End point values | Insulin degludec | Insulin glargine | | |
|-----------------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3818 | 3819 | | |
| Units: Number of subjects | | | | |
| First EAC-confirmed MACE | 325 | 356 | | |
| Myocardial infarction (non-fatal) | 143 | 163 | | |

| | | | | |
|----------------------|-----|-----|--|--|
| Stroke (non-fatal) | 68 | 74 | | |
| Cardiovascular death | 114 | 119 | | |

Statistical analyses

| Statistical analysis title | Statistical analysis |
|--|-------------------------------------|
| Statistical analysis description: The hazard ratio (HR) (IDeg vs IGlär) was based on Cox regression with investigational medicinal product as only factor for primary analysis. | |
| Comparison groups | Insulin glargine v Insulin degludec |
| Number of subjects included in analysis | 7637 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority ^[1] |
| P-value | < 0.001 ^[2] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.908 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.781 |
| upper limit | 1.055 |

Notes:

[1] - Non-inferiority of IDeg to IGlär was considered confirmed if the upper limit of the two-sided 95% confidence interval for the HR was below 1.3 or equivalent if the p-value for the one-sided test of null hypothesis (H₀): HR ≥ 1.3 against the alternative hypothesis (H_a): HR < 1.3 was less than 2.5%.

[2] - p value : Refers to one-sided test of HR ≥ 1.3 (against H_a: HR < 1.3).

Secondary: Number of EAC-confirmed severe hypoglycaemic episodes

| | |
|--|---|
| End point title | Number of EAC-confirmed severe hypoglycaemic episodes |
| End point description: Number of severe hypoglycaemic episodes from week 0 to the last assessment (up to 35.6 months). The episode of severe hypoglycaemia is an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. The trial was event driven and planned to last up to a maximum of 60.5 months. The actual trial duration (time from first subject first visit to last subject last visit) was 35.6 months. The maximum trial duration for a single subject was 33.1 months. The analysis was based on the FAS, which included all randomised subjects. | |
| End point type | Secondary |
| End point timeframe: From randomisation to individual end of trial (maximum patient year observation: 2.75 years) | |

| End point values | Insulin degludec | Insulin glargine | | |
|----------------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3818 | 3819 | | |
| Units: Number of severe episodes | 280 | 472 | | |

Statistical analyses

| Statistical analysis title | Statistical analysis |
|---|-------------------------------------|
| Statistical analysis description: The model included treatment (IDeg vs IGLar) as a fixed factor and was fitted using the FAS. | |
| Comparison groups | Insulin degludec v Insulin glargine |
| Number of subjects included in analysis | 7637 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[3] |
| P-value | < 0.001 ^[4] |
| Method | Negative binomial regression |
| Parameter estimate | Rate Ratio |
| Point estimate | 0.601 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.476 |
| upper limit | 0.759 |

Notes:

[3] - Superiority was considered confirmed if the upper limit of the two-sided 95% confidence interval for the rate ratio (RR) was below 1.0 or equivalent if the p-value for the one-sided test of H0: RR ≥ 1.0 against Ha: RR < 1.0, was less than 2.5%.

[4] - p-value : Refers to one-sided test of RR ≥ 1.0 (against Ha: RR < 1.0)

Secondary: Occurrence of at least one EAC confirmed severe hypoglycaemic episode within a subject (yes/no)

| | |
|-----------------|---|
| End point title | Occurrence of at least one EAC confirmed severe hypoglycaemic episode within a subject (yes/no) |
|-----------------|---|

End point description:

Occurrence of at least one EAC-confirmed severe hypoglycaemic episode within a subject from week 0 to the last assessment (up to 35.6 months). The episode of severe hypoglycaemia is an episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. The analysis was based on the FAS, which included all randomised subjects.

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

End point timeframe:

From randomisation to individual end of trial date (maximum patient year observation: 2.75 years)

| End point values | Insulin degludec | Insulin glargine | | |
|-----------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3818 | 3819 | | |
| Units: Number of subjects | 187 | 252 | | |

Statistical analyses

| Statistical analysis title | Statistical analysis |
|--|-------------------------------------|
| Statistical analysis description: | |
| The model was logistic regression with log-link function. The model included treatment (IDeg vs IGlar) as a fixed factor and was fitted using the FAS. | |
| Comparison groups | Insulin degludec v Insulin glargine |
| Number of subjects included in analysis | 7637 |
| Analysis specification | Pre-specified |
| Analysis type | superiority ^[5] |
| P-value | < 0.001 ^[6] |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.729 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 0.866 |

Notes:

[5] - Superiority of IDeg to IGlar was considered confirmed if the upper limit of the two-sided 95% confidence interval for the odds ratio (OR) was below 1.0 or equivalent if the p-value for the one-sided test of H0: OR ≥ 1.0 against Ha: OR < 1.0, was less than 2.5%.

[6] - p-value: Refers to one-sided test of OR ≥ 1.0 (against Ha: OR < 1.0)

Secondary: Change in Glycosylated haemoglobin (HbA1c)

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|--|--|
| End point title | Change in Glycosylated haemoglobin (HbA1c) |
| End point description: | |
| Mean change in HbA1c from week 0 to month 24. The analysis was based on the FAS. The number of subjects analysed are the number of subjects with the available data after 24 months. | |
| End point type | Secondary |
| End point timeframe: | |
| Randomisation to 24 months | |

| End point values | Insulin degludec | Insulin glargine | | |
|--------------------------------------|------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2431 | 2404 | | |
| Units: percentage of HbA1c | | | | |
| arithmetic mean (standard deviation) | -0.86 (± 1.51) | -0.84 (± 1.57) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

The AEs were considered from randomisation visit (week 0) to follow up visit (end of treatment plus at least 30 days). The trial was event driven and planned to last up to a maximum of 60.5 months.
Maximum trial duration for single subject: 33.1 months

Adverse event reporting additional description:

Safety was summarised using the FAS, which included all randomised subjects. Number of deaths causally related to treatment' is the data considered to present under 'total number of deaths resulting from adverse events.

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

Dictionary used

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

| | |
|--------------------|----|
| Dictionary version | 19 |
|--------------------|----|

Reporting groups

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|-----------------------|------|
| Reporting group title | IDeg |
|-----------------------|------|

Reporting group description:

Subjects received IDeg 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pre-trial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IDeg). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IDeg OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IDeg OD, and the bolus component was calculated and switched to IAsp. The trial was event driven for with a realised observation period up to 33 months.

| | |
|-----------------------|-------|
| Reporting group title | IGlar |
|-----------------------|-------|

Reporting group description:

Subjects received IGlar 100 units/mL OD subcutaneously (S.C.; under the skin) in the thigh, upper arm, or the abdominal wall between dinner and bedtime. Subjects continued their pretrial medication except for the basal insulin, which was replaced by investigational medicinal product (IMP; IGlar). The pre-trial bolus insulin was allowed and could be replaced with IAsp at the discretion of the investigator. For subjects previously receiving premixed/biphasic insulin the basal component was calculated and switched to IGlar OD, and the bolus insulin component to bolus insulin. For subjects previously receiving premixed/biphasic insulin BID, the total basal component was calculated, reduced by 20- 30% and switched to IGlar OD, and the bolus component was calculated and switched to IAsp. The trial was event driven with a realized treatment period up to 33 months.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Systematic collection of AEs was limited to SAEs, AEs leading to permanent discontinuation of IMP, medication errors leading to SAEs, and AEs related technical complaints and were summarised. Non-serious AEs not fulfilling the above criteria were not systematically collected.

| Serious adverse events | IDeg | IGlar | |
|---|-------------------------|-------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1473 / 3818 (38.58%) | 1517 / 3819 (39.72%) | |
| number of deaths (all causes) | 202 | 221 | |
| number of deaths resulting from adverse events | 6 | 12 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute leukaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute lymphocytic leukaemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Adenocarcinoma gastric | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Adenocarcinoma of colon | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma pancreas | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal adenoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal neoplasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adult T-cell lymphoma/leukaemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| B-cell lymphoma | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| B-cell lymphoma stage III | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of bladder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of thyroid gland | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign ovarian tumour | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct adenocarcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer recurrent | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer stage 0, with cancer in situ | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma recurrent | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder transitional cell carcinoma stage I | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bowen's disease | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer metastatic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Breast cancer stage I | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer stage II | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer stage IV | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac valve fibroelastoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangiocarcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Choroid melanoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon adenoma | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Colon cancer stage III | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer metastatic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diffuse large B-cell lymphoma recurrent | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Endometrial adenocarcinoma | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibroma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder adenocarcinoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder cancer metastatic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastrointestinal cancer metastatic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastrointestinal tract adenoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Hepatic cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hepatic neoplasm | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 1 / 3 | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Leiomyoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukaemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung adenocarcinoma metastatic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Lung adenocarcinoma stage II | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung adenocarcinoma stage IV | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung cancer metastatic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lymphoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma in situ | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant peritoneal neoplasm | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Meningioma benign | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesothelioma malignant | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastases to liver | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Metastases to lung | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastases to lymph nodes | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic neoplasm | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastatic renal cell carcinoma | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Metastatic squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mucinous endometrial carcinoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma metastatic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Non-small cell lung cancer | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Non-small cell lung cancer stage I | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal carcinoma | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ovarian cancer recurrent | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cancer stage IV | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Pancreatic carcinoma metastatic | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 2 | 0 / 0 | |
| Pancreatic carcinoma stage IV | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Papillary cystadenoma lymphomatosum | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary thyroid cancer | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Parathyroid tumour benign | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Penile squamous cell carcinoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phaeochromocytoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pituitary tumour benign | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma cell myeloma | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 11 / 3818 (0.29%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer stage I | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer stage II | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Rectal adenoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer metastatic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer metastatic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland cancer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Small cell lung cancer extensive stage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer metastatic | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Soft tissue sarcoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Squamous cell carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the tongue | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular seminoma (pure) stage I | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testis cancer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsil cancer | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tumour of ampulla of Vater | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric cancer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Aneurysm | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiopathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stenosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Arterial haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Blood pressure inadequately controlled | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 13 / 3818 (0.34%) | 10 / 3819 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dry gangrene | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Embolism arterial | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism venous | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Essential hypertension | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypertension | | | |
| subjects affected / exposed | 17 / 3818 (0.45%) | 23 / 3819 (0.60%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 14 / 3818 (0.37%) | 14 / 3819 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypovolaemic shock | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermittent claudication | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic limb pain | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Leriche syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphocele | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant hypertension | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microangiopathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive shock | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Orthostatic hypotension | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 13 / 3818 (0.34%) | 12 / 3819 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral embolism | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | 3 / 3818 (0.08%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 14 / 3819 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral venous disease | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phlebitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reperfusion injury | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian steal syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Superior vena cava stenosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Temporal arteritis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular insufficiency | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Abdominal hernia repair | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal panniculectomy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amputation | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angioplasty | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm repair | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stent insertion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve replacement | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula operation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ablation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac pacemaker battery replacement | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac pacemaker insertion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac pacemaker replacement | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract operation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colectomy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colostomy closure | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary arterial stent insertion | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery bypass | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal switch | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrectomy | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric bypass | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia repair | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip arthroplasty | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hysterectomy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implantable defibrillator insertion | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implantable defibrillator replacement | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia repair | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc operation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-ocular injection | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jejunostomy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint arthroplasty | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Knee arthroplasty | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Knee operation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic surgery | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagectomy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff repair | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Roux loop conversion | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal decompression | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fusion surgery | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroidectomy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transurethral prostatectomy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia repair | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac complication associated with device | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac death | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Catheter site haematoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 16 / 3818 (0.42%) | 21 / 3819 (0.55%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 22 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complication associated with device | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyst | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 27 / 3818 (0.71%) | 21 / 3819 (0.55%) | |
| occurrences causally related to treatment / all | 0 / 27 | 2 / 21 | |
| deaths causally related to treatment / all | 0 / 27 | 2 / 21 | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body reaction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised oedema | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 3818 (0.10%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Impaired healing | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Local swelling | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 47 / 3818 (1.23%) | 54 / 3819 (1.41%) | |
| occurrences causally related to treatment / all | 0 / 48 | 0 / 63 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema due to cardiac disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyp | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden cardiac death | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Sudden death | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 8 | |
| Surgical failure | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic inflammatory response syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent restenosis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent stenosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent thrombosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic shock | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal transplant failure | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |

| | | | |
|---|------------------|------------------|--|
| Social stay hospitalisation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 9 / 3818 (0.24%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast enlargement | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical cyst | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical dysplasia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix haemorrhage uterine | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystocele | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|------------------|------------------|--|
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectocele | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine mass | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine prolapse | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | | | |

| | | | |
|---|-------------------|-------------------|--|
| Acquired diaphragmatic eventration | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute pulmonary oedema | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 24 / 3818 (0.63%) | 31 / 3819 (0.81%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 35 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 8 | |
| Asthma | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma-chronic obstructive pulmonary disease overlap syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atelectasis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic obstructive pulmonary disease | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 42 / 3818 (1.10%) | 56 / 3819 (1.47%) | |
| occurrences causally related to treatment / all | 0 / 54 | 0 / 70 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 5 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 17 / 3819 (0.45%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea paroxysmal nocturnal | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Idiopathic pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Laryngeal stenosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal polyps | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal septum deviation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-cardiogenic pulmonary oedema | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive airways disorder | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal oedema | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pickwickian syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pleurisy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pneumothorax | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pneumothorax spontaneous | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary congestion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 15 / 3818 (0.39%) | 10 / 3819 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 15 | 2 / 10 | |
| deaths causally related to treatment / all | 0 / 5 | 1 / 1 | |
| Pulmonary fibrosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pulmonary sarcoidosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary veno-occlusive disease | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Respiratory distress | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 22 / 3818 (0.58%) | 18 / 3819 (0.47%) | |
| occurrences causally related to treatment / all | 1 / 23 | 0 / 19 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 4 | |
| Respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Acute stress disorder | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Affective disorder | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aggression | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Agitation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar disorder | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Completed suicide | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Confusional state | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 5 / 3818 (0.13%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression suicidal | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hallucination, visual | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional self-injury | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Major depression | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paranoia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Personality change due to a general medical condition | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post stroke depression | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic stress disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizoaffective disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizoaffective disorder bipolar type | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizophrenia | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device dislocation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device failure | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device fastener issue | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device inappropriate shock delivery | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device lead damage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device loosening | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device malfunction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lead dislodgement | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Acute hepatic failure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Alcoholic liver disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct obstruction | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stone | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary dyskinesia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis chronic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic hepatic failure | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Dilatation intrahepatic duct acquired | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cirrhosis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Hepatic failure | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic lesion | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis chronic active | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatorenal syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ischaemic hepatitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Jaundice | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver disorder | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Non-alcoholic steatohepatitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal vein thrombosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sphincter of Oddi dysfunction | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Steatohepatitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Arteriogram coronary | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biopsy lung | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose decreased | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose increased | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood magnesium decreased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium decreased | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure increased | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac monitoring | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheterisation cardiac | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulation time prolonged | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ejection fraction decreased | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram ST segment abnormal | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram ST segment elevation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram ST-T change | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical observation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin increased | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | | | |

| | | | |
|---|------------------|------------------|--|
| Accident at work | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental overdose | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol poisoning | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia postoperative | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaesthetic complication | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaesthetic complication pulmonary | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anastomotic ulcer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brachial plexus injury | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns third degree | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac valve replacement complication | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery restenosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary vascular graft occlusion | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Drug administration error | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extra dose administered | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial bones fracture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 54 / 3818 (1.41%) | 55 / 3819 (1.44%) | |
| occurrences causally related to treatment / all | 3 / 57 | 0 / 59 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Femoral neck fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal anastomotic leak | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal injury | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stoma complication | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrostomy tube site complication | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Humerus fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ilium fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated incisional hernia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site haemorrhage | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional overdose | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint dislocation | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laceration | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament rupture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple fractures | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple injuries | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle strain | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Overdose | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax traumatic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post concussion syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Post procedural myocardial infarction | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative fever | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative ileus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative respiratory failure | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative thoracic procedure complication | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound complication | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural complication | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural hypotension | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural intestinal perforation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary contusion | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 20 / 3818 (0.52%) | 18 / 3819 (0.47%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 2 | |
| Seroma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stab wound | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stoma site reaction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haematoma | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon rupture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal burn | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transfusion-related acute lung injury | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haematoma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric injury | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular procedure complication | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrong drug administered | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Congenital ureterocele | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Factor V deficiency | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal arteriovenous malformation | | | |

| | | | |
|---|-------------------|--------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic arteriovenous malformation | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic cardiomyopathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteogenesis imperfecta | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phimosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 2 / 12 | 1 / 8 | |
| deaths causally related to treatment / all | 1 / 1 | 1 / 1 | |
| Acute left ventricular failure | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 98 / 3818 (2.57%) | 115 / 3819 (3.01%) | |
| occurrences causally related to treatment / all | 4 / 111 | 6 / 123 | |
| deaths causally related to treatment / all | 0 / 6 | 0 / 14 | |
| Angina pectoris | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 36 / 3818 (0.94%) | 48 / 3819 (1.26%) | |
| occurrences causally related to treatment / all | 0 / 37 | 2 / 53 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Angina unstable | | | |
| subjects affected / exposed | 87 / 3818 (2.28%) | 79 / 3819 (2.07%) | |
| occurrences causally related to treatment / all | 8 / 94 | 3 / 93 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Aortic valve disease | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 5 | |
| Arteriospasm coronary | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 47 / 3818 (1.23%) | 56 / 3819 (1.47%) | |
| occurrences causally related to treatment / all | 0 / 55 | 0 / 75 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Atrial flutter | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 11 / 3818 (0.29%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial tachycardia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular dissociation | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block left | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block right | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 26 / 3818 (0.68%) | 20 / 3819 (0.52%) | |
| occurrences causally related to treatment / all | 0 / 26 | 3 / 21 | |
| deaths causally related to treatment / all | 0 / 24 | 3 / 16 | |
| Cardiac discomfort | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiac failure | | | |
| subjects affected / exposed | 24 / 3818 (0.63%) | 30 / 3819 (0.79%) | |
| occurrences causally related to treatment / all | 1 / 26 | 0 / 33 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 4 | |
| Cardiac failure acute | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Cardiac failure chronic | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 10 / 3819 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cardiac failure congestive | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 134 / 3818 (3.51%) | 143 / 3819 (3.74%) | |
| occurrences causally related to treatment / all | 2 / 177 | 5 / 206 | |
| deaths causally related to treatment / all | 0 / 13 | 2 / 12 | |
| Cardiac hypertrophy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac ventricular thrombosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 12 / 3818 (0.31%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 12 | 0 / 8 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Cardiomegaly | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Cardiorenal syndrome | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiovascular disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Chordae tendinae rupture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic left ventricular failure | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congestive cardiomyopathy | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cor pulmonale | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cor pulmonale acute | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 80 / 3818 (2.10%) | 89 / 3819 (2.33%) | |
| occurrences causally related to treatment / all | 4 / 85 | 1 / 91 | |
| deaths causally related to treatment / all | 1 / 5 | 0 / 4 | |
| Coronary artery dissection | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery embolism | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery insufficiency | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 12 / 3818 (0.31%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery stenosis | | | |
| subjects affected / exposed | 12 / 3818 (0.31%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary ostial stenosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diastolic dysfunction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart valve incompetence | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive cardiomyopathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive heart disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Intracardiac thrombus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic cardiomyopathy | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Left ventricular dysfunction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left ventricular hypertrophy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Long QT syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 48 / 3818 (1.26%) | 66 / 3819 (1.73%) | |
| occurrences causally related to treatment / all | 0 / 51 | 3 / 68 | |
| deaths causally related to treatment / all | 0 / 15 | 0 / 16 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Nodal arrhythmia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prinzmetal angina | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulseless electrical activity | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Restrictive cardiomyopathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Right ventricular failure | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Silent myocardial infarction | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus arrest | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress cardiomyopathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systolic dysfunction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachyarrhythmia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Tachycardia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tricuspid valve incompetence | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trifascicular block | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular extrasystoles | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 1 | |
| Ventricular hypokinesia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 12 / 3819 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphasia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ataxia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Balance disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain injury | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Brain stem haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Brain stem infarction | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain stem stroke | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery disease | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |
| subjects affected / exposed | 15 / 3818 (0.39%) | 14 / 3819 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar infarction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cerebral arteriosclerosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | |
| Cerebral infarction | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral small vessel ischaemic disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 22 / 3819 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 11 | 2 / 23 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 6 | |
| Cervical myelopathy | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cranial nerve paralysis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia Alzheimer's type | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diabetic mononeuropathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic neuropathy | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Dysarthria | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolic cerebral infarction | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolic stroke | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Encephalopathy | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 6 / 3818 (0.16%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Epidural lipomatosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Essential tremor | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paralysis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised tonic-clonic seizure | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Guillain-Barre syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 3 | |
| Haemorrhagic cerebral infarction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Haemorrhagic stroke | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Haemorrhagic transformation stroke | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiplegic migraine | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocephalus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hyperglycaemic seizure | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive encephalopathy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic seizure | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 5 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic unconsciousness | | | |
| subjects affected / exposed | 27 / 3818 (0.71%) | 29 / 3819 (0.76%) | |
| occurrences causally related to treatment / all | 19 / 29 | 23 / 33 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Hypoxic-ischaemic encephalopathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IIIrd nerve paralysis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intensive care unit acquired weakness | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial aneurysm | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Intracranial pressure increased | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ischaemic cerebral infarction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 43 / 3818 (1.13%) | 45 / 3819 (1.18%) | |
| occurrences causally related to treatment / all | 3 / 44 | 3 / 50 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Lacunar infarction | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lacunar stroke | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lethargy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 4 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar radiculopathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Memory impairment | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 7 | 2 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Migraine | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine-triggered seizure | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mononeuropathy multiplex | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Motor neurone disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple sclerosis relapse | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myasthenia gravis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve root compression | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normal pressure hydrocephalus | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinson's disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-injection delirium sedation syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 12 / 3819 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radicular pain | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiculopathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reversible ischaemic neurological deficit | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Senile dementia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord compression | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitic myelopathy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status epilepticus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Syncope | | | |
| subjects affected / exposed | 25 / 3818 (0.65%) | 24 / 3819 (0.63%) | |
| occurrences causally related to treatment / all | 3 / 27 | 0 / 29 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thalamic infarction | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thalamus haemorrhage | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Thrombotic stroke | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic encephalopathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient global amnesia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 28 / 3818 (0.73%) | 42 / 3819 (1.10%) | |
| occurrences causally related to treatment / all | 1 / 29 | 2 / 44 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tremor | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulnar nerve palsy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VIth nerve paralysis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular dementia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Vascular headache | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar insufficiency | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual field defect | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 34 / 3819 (0.89%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 40 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulopathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coombs negative haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Evans syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic anaemia | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypochromic anaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrogenic anaemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normochromic normocytic anaemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inner ear disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniere's disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden hearing loss | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Blindness | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 9 / 3818 (0.24%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 13 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract diabetic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 4 / 3818 (0.10%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glaucoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular fibrosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurotrophic keratopathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Optic ischaemic neuropathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pterygium | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal artery occlusion | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal detachment | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal vein occlusion | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinopathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinopathy proliferative | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia obstructive | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal mass | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 10 / 3818 (0.26%) | 10 / 3819 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acid peptic disease | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute abdomen | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Alcoholic pancreatitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendix disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic gastritis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gastroparesis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal stenosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal vascular ectasia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocoele | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epigastric discomfort | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric antral vascular ectasia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric perforation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer perforation | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroduodenitis haemorrhagic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 10 / 3818 (0.26%) | 15 / 3819 (0.39%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Gastrointestinal polyp haemorrhage | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoidal haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 4 / 3818 (0.10%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus paralytic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Intra-abdominal haematoma | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine polyp | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mallory-Weiss syndrome | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric haematoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenic colitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal rupture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal varices haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic mass | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 7 / 3818 (0.18%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 6 / 3818 (0.16%) | 11 / 3819 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer perforation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periodontal disease | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumatosis intestinalis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal ulcer haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland calculus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland mass | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 9 / 3818 (0.24%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spigelian hernia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varices oesophageal | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 5 / 3818 (0.13%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 1 / 5 | 1 / 7 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 1 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 2 / 4 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Dermal cyst | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot | | | |
| subjects affected / exposed | 10 / 3818 (0.26%) | 11 / 3819 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 10 | 2 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic neuropathic ulcer | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hidradenitis | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Hypersensitivity vasculitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathic ulcer | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pemphigoid | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin necrosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Skin ulcer | | | |
| subjects affected / exposed | 13 / 3818 (0.34%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Skin ulcer haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stasis dermatitis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 70 / 3818 (1.83%) | 95 / 3819 (2.49%) | |
| occurrences causally related to treatment / all | 0 / 79 | 2 / 110 | |
| deaths causally related to treatment / all | 0 / 9 | 0 / 6 | |
| Acute prerenal failure | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anuria | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Azotaemia | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Bladder neck obstruction | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder outlet obstruction | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus bladder | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urinary | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 16 / 3818 (0.42%) | 26 / 3819 (0.68%) | |
| occurrences causally related to treatment / all | 3 / 18 | 0 / 30 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 1 | |
| Cystitis noninfective | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic nephropathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End stage renal disease | | | |
| subjects affected / exposed | 12 / 3818 (0.31%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 1 / 12 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 3 | |
| Glomerulonephritis rapidly progressive | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Nephropathy toxic | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrosclerosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal artery stenosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 14 / 3818 (0.37%) | 17 / 3819 (0.45%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Renal impairment | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal mass | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal tubular necrosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stag horn calculus | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress urinary incontinence | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary hesitation | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 9 / 3818 (0.24%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Goitre | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid mass | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic goitre | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic nodular goitre | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Ankle deformity | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropathy | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back disorder | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 7 / 3818 (0.18%) | 12 / 3819 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical spinal stenosis | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis pyrophosphate | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costochondritis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dactylitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enthesopathy | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exostosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Flank pain | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot deformity | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gouty arthritis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemarthrosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 9 / 3818 (0.24%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint effusion | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 12 / 3818 (0.31%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle spasms | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck pain | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 32 / 3818 (0.84%) | 30 / 3819 (0.79%) | |
| occurrences causally related to treatment / all | 0 / 35 | 0 / 31 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteopenia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoporosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyarthritis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudarthrosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Rotator cuff syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue necrosis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal column stenosis | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon disorder | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendonitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral foraminal stenosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal sepsis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Abdominal wall abscess | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall infection | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess limb | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess rupture | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess soft tissue | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute endocarditis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 4 / 3818 (0.10%) | 6 / 3819 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerotic gangrene | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial pyelonephritis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial sepsis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Beta haemolytic streptococcal infection | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 16 / 3818 (0.42%) | 21 / 3819 (0.55%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis bacterial | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter site infection | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 52 / 3818 (1.36%) | 61 / 3819 (1.60%) | |
| occurrences causally related to treatment / all | 1 / 64 | 1 / 72 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cellulitis orbital | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis staphylococcal | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis streptococcal | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest wall abscess | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis infective | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic abscess | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dengue fever | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Dermatitis infected | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot infection | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 8 / 3819 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gangrene | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disseminated cryptococcosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 14 / 3819 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysentery | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema infected | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Empyema | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiglottitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| External ear cellulitis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural abscess | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gangrene | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 13 / 3819 (0.34%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gas gangrene | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 13 / 3818 (0.34%) | 12 / 3819 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Escherichia coli | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft infection | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin abscess | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| H1N1 influenza | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helicobacter gastritis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site infection | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected bite | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| 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 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected seroma | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected skin ulcer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious colitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Infusion site infection | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral discitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint abscess | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella sepsis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Labyrinthitis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Localised infection | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lyme disease | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis aseptic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis viral | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mucormycosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotising fasciitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal candidiasis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 20 / 3818 (0.52%) | 22 / 3819 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis acute | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis chronic | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis externa | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media chronic | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraspinal abscess | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paronychia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perineal abscess | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirectal abscess | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritoneal abscess | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pilonidal cyst | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 90 / 3818 (2.36%) | 90 / 3819 (2.36%) | |
| occurrences causally related to treatment / all | 1 / 99 | 1 / 102 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 4 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia klebsiella | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia mycoplasmal | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia pneumococcal | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia staphylococcal | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia streptococcal | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia viral | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural cellulitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (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 | 8 / 3818 (0.21%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural sepsis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative abscess | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate infection | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis Escherichia coli | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudomonal bacteraemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 11 / 3819 (0.29%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyuria | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal abscess | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal abscess | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory syncytial virus bronchitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salpingitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 36 / 3818 (0.94%) | 31 / 3819 (0.81%) | |
| occurrences causally related to treatment / all | 1 / 37 | 1 / 31 | |
| deaths causally related to treatment / all | 0 / 7 | 0 / 5 | |
| Sepsis pasteurella | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sepsis syndrome | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic arthritis staphylococcal | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic embolus | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 12 / 3819 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 5 | |
| Sialoadenitis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue infection | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal abscess | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Streptococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal sepsis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdiaphragmatic abscess | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 34 / 3818 (0.89%) | 30 / 3819 (0.79%) | |
| occurrences causally related to treatment / all | 0 / 37 | 0 / 37 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection bacterial | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 10 / 3818 (0.26%) | 9 / 3819 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Viraemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 3 / 3819 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral pericarditis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval abscess | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 23 / 3818 (0.60%) | 16 / 3819 (0.42%) | |
| occurrences causally related to treatment / all | 0 / 23 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 3 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 4 / 3819 (0.10%) | |
| occurrences causally related to treatment / all | 2 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Diabetic complication | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 5 / 3818 (0.13%) | 14 / 3819 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diabetic metabolic decompensation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failure to thrive | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid overload | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gout | | | |
| subjects affected / exposed | 4 / 3818 (0.10%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperammonaemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 11 / 3818 (0.29%) | 16 / 3819 (0.42%) | |
| occurrences causally related to treatment / all | 1 / 12 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 18 / 3818 (0.47%) | 22 / 3819 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypernatraemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 64 / 3818 (1.68%) | 49 / 3819 (1.28%) | |
| occurrences causally related to treatment / all | 57 / 77 | 38 / 66 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 5 / 3819 (0.13%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 0 / 3819 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 8 / 3818 (0.21%) | 7 / 3819 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 2 / 3818 (0.05%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactic acidosis | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 2 / 3819 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 3 / 3818 (0.08%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Obesity | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 3818 (0.08%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudohyponatraemia | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 1 / 3818 (0.03%) | 1 / 3819 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |

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

| Non-serious adverse events | IDeg | IGlar | |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 3818 (0.00%) | 0 / 3819 (0.00%) | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---|
| 07 April 2014 | The following changes were made: 1. Clarification on how to document and evaluate eligibility and treatment continuation. 2. Additional secondary endpoints, and statistical considerations, with reference to the SAP. 3. Storage conditions for open (in-use) IMP was omitted 4. The process for external evaluation of hypoglycaemia was clarified. 5. Update of the reference for the Helsinki Declaration. 6. Minor corrections, clarifications and updates. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported