

**Clinical trial results:****A Long-Term Outcomes Study to Assess STatin Residual Risk Reduction with EpaNova in HiGH Cardiovascular Risk PatientTs with Hypertriglyceridemia (STRENGTH)****Summary**

| | |
|--------------------------|-------------------------------|
| EudraCT number | 2014-001069-28 |
| Trial protocol | CZ GB EE LT HU IT DK NL PL BE |
| Global end of trial date | 27 May 2020 |

Results information

| | |
|--------------------------------|---|
| Result version number | v2 (current) |
| This version publication date | 26 September 2021 |
| First version publication date | 10 June 2021 |
| Version creation reason | • Correction of full data set We revised FSR date. |

Trial information**Trial identification**

| | |
|-----------------------|-------------|
| Sponsor protocol code | D5881C00004 |
|-----------------------|-------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | AstraZeneca AB |
| Sponsor organisation address | 151 85, Södertälje, Sweden, |
| Public contact | AstraZeneca Information Center, AstraZeneca, +1 18772409479, information.center@astrazeneca.com |
| Scientific contact | Global Clinical Lead, AstraZeneca, +1 18772409479, information.center@astrazeneca.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 | 22 July 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 27 May 2020 |
| Global end of trial reached? | Yes |
| Global end of trial date | 27 May 2020 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the effectiveness of adding Epanova to statin therapy (with or without ezetimibe) for lowering MACE (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, emergent/elective coronary revascularization, or hospitalization for unstable angina) in high cardiovascular risk patients with persistent hypertriglyceridemia and low high-density lipoprotein cholesterol.

Protection of trial subjects:

This study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with International Council for Harmonisation/GCP, applicable regulatory requirements, and the AstraZeneca policy on Bioethics and Human Biological Samples.

Background therapy:

Background statin therapy

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 30 October 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Australia: 112 |
| Country: Number of subjects enrolled | Belgium: 104 |
| Country: Number of subjects enrolled | Canada: 364 |
| Country: Number of subjects enrolled | Czechia: 228 |
| Country: Number of subjects enrolled | Denmark: 121 |
| Country: Number of subjects enrolled | Estonia: 110 |
| Country: Number of subjects enrolled | Hungary: 1123 |
| Country: Number of subjects enrolled | Italy: 67 |
| Country: Number of subjects enrolled | Japan: 305 |
| Country: Number of subjects enrolled | Lithuania: 363 |
| Country: Number of subjects enrolled | Mexico: 307 |
| Country: Number of subjects enrolled | Netherlands: 421 |
| Country: Number of subjects enrolled | New Zealand: 151 |
| Country: Number of subjects enrolled | Poland: 993 |
| Country: Number of subjects enrolled | Russian Federation: 633 |
| Country: Number of subjects enrolled | South Africa: 961 |

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Korea, Republic of: 133 |
| Country: Number of subjects enrolled | Taiwan: 59 |
| Country: Number of subjects enrolled | Ukraine: 1964 |
| Country: Number of subjects enrolled | United Kingdom: 759 |
| Country: Number of subjects enrolled | United States: 3087 |
| Country: Number of subjects enrolled | China: 713 |
| Worldwide total number of subjects | 13078 |
| EEA total number of subjects | 3530 |

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) | 7459 |
| From 65 to 84 years | 5563 |
| 85 years and over | 56 |

Subject disposition

Recruitment

Recruitment details:

686 study sites in 22 countries randomized subjects. The first patient was randomized on 11 November 2014. The last patient was randomized on 12 July 2017.

Pre-assignment

Screening details:

In total, 33047 patients were enrolled, with 13078 patients randomized (6539 patients were randomized to Epanova and 6539 to placebo). Among the randomized patients, 7 in the Epanova group and 4 in the placebo group did not receive study treatment.

Period 1

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

Arms

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

Arm description:

Omega-3 carboxylic acid 4 x 1 gram capsule

| | |
|--|-------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Omega-3 carboxylic acid |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

4 x 1 gram capsule orally once daily

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

Arm description:

Corn oil 4 x 1 gram capsule

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

Dosage and administration details:

4 x 1 gram capsule orally once daily

| Number of subjects in period 1 | Epanova | Placebo |
|---------------------------------------|---------|---------|
| Started | 6539 | 6539 |
| Completed | 80 | 92 |
| Not completed | 6459 | 6447 |
| Adverse event, serious fatal | 363 | 330 |
| Consent withdrawn by subject | 111 | 78 |
| Study terminated by sponsor | 5854 | 5901 |
| Other reasons | 128 | 135 |
| Lost to follow-up | 3 | 2 |
| Protocol deviation | - | 1 |

Baseline characteristics

Reporting groups

| | |
|--|---------|
| Reporting group title | Epanova |
| Reporting group description: Omega-3 carboxylic acid 4 x 1 gram capsule | |
| Reporting group title | Placebo |
| Reporting group description: Corn oil 4 x 1 gram capsule | |

| Reporting group values | Epanova | Placebo | Total |
|---|---------|---------|-------|
| Number of subjects | 6539 | 6539 | 13078 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 3756 | 3703 | 7459 |
| From 65-84 years | 2758 | 2805 | 5563 |
| 85 years and over | 25 | 31 | 56 |
| Age Continuous Units: years | | | |
| arithmetic mean | 62.5 | 62.5 | |
| standard deviation | ± 8.98 | ± 8.98 | - |
| Sex: Female, Male Units: Participants | | | |
| Male | 4250 | 4260 | 8510 |
| Female | 2289 | 2279 | 4568 |
| Race (NIH/OMB) Units: Subjects | | | |
| WHITE | 5341 | 5382 | 10723 |
| BLACK OR AFRICAN AMERICAN | 180 | 166 | 346 |
| ASIAN | 698 | 657 | 1355 |
| NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER | 10 | 11 | 21 |
| AMERICAN INDIAN OR ALASKA NATIVE | 114 | 112 | 226 |
| OTHER | 159 | 154 | 313 |
| MULTIPLE | 33 | 47 | 80 |
| UNKNOWN | 4 | 10 | 14 |
| NOT REPORTED | 0 | 0 | 0 |
| Region of Enrollment Units: Subjects | | | |
| Australia | 58 | 54 | 112 |
| Belgium | 53 | 51 | 104 |

| | | | |
|---------------------------|------|------|------|
| Canada | 187 | 177 | 364 |
| China | 357 | 356 | 713 |
| Czech Republic | 120 | 108 | 228 |
| Denmark | 48 | 73 | 121 |
| Estonia | 57 | 53 | 110 |
| Hungary | 561 | 562 | 1123 |
| Italy | 33 | 34 | 67 |
| Japan | 166 | 139 | 305 |
| Korea, Republic Of | 68 | 65 | 133 |
| Lithuania | 170 | 193 | 363 |
| Mexico | 152 | 155 | 307 |
| Netherlands | 206 | 215 | 421 |
| New Zealand | 74 | 77 | 151 |
| Poland | 501 | 492 | 993 |
| Russia | 307 | 326 | 633 |
| South Africa | 471 | 490 | 961 |
| Taiwan, Province Of China | 28 | 31 | 59 |
| Ukraine | 1009 | 955 | 1964 |
| United Kingdom | 377 | 382 | 759 |
| USA | 1536 | 1551 | 3087 |

End points

End points reporting groups

| | |
|---|---------------------|
| Reporting group title | Epanova |
| Reporting group description: Omega-3 carboxylic acid 4 x 1 gram capsule | |
| Reporting group title | Placebo |
| Reporting group description: Corn oil 4 x 1 gram capsule | |
| Subject analysis set title | Full analysis set |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Full analysis set contains all subjects who were randomised | |
| Subject analysis set title | Safety analysis set |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Safety analysis set contains all randomised subjects who received at least 1 dose of investigational product | |

Primary: The primary outcome measure is the time to the first occurrence of any component of the composite of Major adverse cardiovascular events (MACE)

| | |
|---|---|
| End point title | The primary outcome measure is the time to the first occurrence of any component of the composite of Major adverse cardiovascular events (MACE) |
| End point description: MACE components include: cardiovascular (CV) death, nonfatal myocardial infarction (MI), nonfatal stroke, emergent/elective coronary revascularization, or hospitalization for unstable angina. | |
| End point type | Primary |
| End point timeframe: From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure | |

| End point values | Epanova | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | 785 | 795 | | |

Statistical analyses

| | |
|--|---------------------------|
| Statistical analysis title | Primary Endpoint Analysis |
| Statistical analysis description: Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region | |
| Comparison groups | Placebo v Epanova |

| | |
|---|------------------------|
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.837 ^[1] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.09 |

Notes:

[1] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of the composite measure of MACE in participants with established CV disease(CVD) at baseline

| | |
|-----------------|--|
| End point title | Time to the first occurrence of the composite measure of MACE in participants with established CV disease(CVD) at baseline |
|-----------------|--|

End point description:

Time to the first occurrence of the composite measure of MACE that includes the first occurrence of CV death, non-fatal MI, non-fatal stroke, emergent/elective coronary revascularization, or hospitalization for unstable angina in the subgroup of participants with established CVD at baseline

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

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

| End point values | Epanova | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 785 | 795 | | |
| # of participants with events with CVD at baseline | 569 | 610 | | |

Statistical analyses

| | |
|-----------------------------------|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
|-----------------------------------|-----------------------------|

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

| | |
|-------------------|-------------------|
| Comparison groups | Epanova v Placebo |
|-------------------|-------------------|

| | |
|---|------------------------|
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.269 ^[2] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.05 |

Notes:

[2] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke

| | |
|-----------------|---|
| End point title | Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke |
|-----------------|---|

End point description:

Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke

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

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

| End point values | Epanova | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | 541 | 517 | | |

Statistical analyses

| | |
|-----------------------------------|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
|-----------------------------------|-----------------------------|

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

| | |
|---|------------------------|
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.402 ^[3] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.05 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.93 |
| upper limit | 1.19 |

Notes:

[3] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke in the subgroup of participants with established CVD at baseline

| | |
|-----------------|--|
| End point title | Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke in the subgroup of participants with established CVD at baseline |
|-----------------|--|

End point description:

Time to the first occurrence of the composite measure of CV events that include the first occurrence of CV death, non-fatal MI and non-fatal stroke in the subgroup of participants with established CVD at baseline

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

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

| End point values | Epanova | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 541 | 517 | | |
| # of participants with events with CVD at baseline | 383 | 385 | | |

Statistical analyses

| | |
|----------------------------|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
|----------------------------|-----------------------------|

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

| | |
|---|-----------------------|
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.94 ^[4] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.01 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.87 |
| upper limit | 1.16 |

Notes:

[4] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina

| | |
|-----------------|---|
| End point title | Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina |
|-----------------|---|

End point description:

Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death (including death due to acute MI, sudden cardiac death and death due to CV procedure), non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina

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

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

| End point values | Epanova | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | 556 | 616 | | |

Statistical analyses

| | |
|----------------------------|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
|----------------------------|-----------------------------|

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

| | |
|---|------------------------|
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.092 ^[5] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.91 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.02 |

Notes:

[5] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: Time to 1st occurrence of a composite measure of coronary events (includes cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina) in the subgroup of participants with established CVD at baseline

| | |
|-----------------|--|
| End point title | Time to 1st occurrence of a composite measure of coronary events (includes cardiac death, non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina) in the subgroup of participants with established CVD at baseline |
|-----------------|--|

End point description:

Time to the first occurrence of the composite measure of coronary events that include the first occurrence of cardiac death (including death due to acute MI, sudden cardiac death and death due to CV procedures), non-fatal MI, emergent/elective coronary revascularization, or hospitalization for unstable angina in the subgroup of participants with established CVD at baseline

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

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

| End point values | Epanova | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 556 | 616 | | |
| # of participants with events with CVD at baseline | 417 | 493 | | |

Statistical analyses

| | |
|----------------------------|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
|----------------------------|-----------------------------|

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

| | |
|-------------------|-------------------|
| Comparison groups | Epanova v Placebo |
|-------------------|-------------------|

| | |
|---|------------------------|
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.016 ^[6] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.85 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.75 |
| upper limit | 0.97 |

Notes:

[6] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of CV death

| | |
|--|--|
| End point title | Time to the first occurrence of CV death |
| End point description: | |
| The time to the first occurrence of CV death | |
| End point type | Secondary |
| End point timeframe: | |
| From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure | |

| End point values | Epanova | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | 228 | 211 | | |

Statistical analyses

| | |
|---|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
| Statistical analysis description: | |
| Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region | |
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.372 ^[7] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.09 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.31 |

Notes:

[7] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing

Secondary: The time to first occurrence of CV death in the subgroup of participants with established CVD at baseline

| | |
|-----------------|---|
| End point title | The time to first occurrence of CV death in the subgroup of participants with established CVD at baseline |
|-----------------|---|

End point description:

The time to the first occurrence of CV death in the subgroup of participants with established CVD at baseline

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

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

| End point values | Epanova | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 228 | 211 | | |
| # of participants with events with CVD at baseline | 152 | 138 | | |

Statistical analyses

| | |
|----------------------------|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
|----------------------------|-----------------------------|

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction

| | |
|---|-------------------|
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.336 [8] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.12 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.89 |
| upper limit | 1.41 |

Notes:

[8] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of all-cause death

| | |
|-----------------|---|
| End point title | Time to the first occurrence of all-cause death |
|-----------------|---|

End point description:

Time to the first occurrence of death from any cause.

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

End point timeframe:

From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure

| End point values | Epanova | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | 373 | 333 | | |

Statistical analyses

| | |
|----------------------------|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
|----------------------------|-----------------------------|

Statistical analysis description:

Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region

| | |
|-------------------|-------------------|
| Comparison groups | Epanova v Placebo |
|-------------------|-------------------|

| | |
|---|-------|
| Number of subjects included in analysis | 13078 |
|---|-------|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

| | |
|---------|-------------|
| P-value | = 0.112 [9] |
|---------|-------------|

| | |
|--------|-----------------|
| Method | Regression, Cox |
|--------|-----------------|

| | |
|--------------------|-------------------|
| Parameter estimate | Hazard ratio (HR) |
|--------------------|-------------------|

| | |
|----------------|------|
| Point estimate | 1.13 |
|----------------|------|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|------|
| lower limit | 0.97 |
|-------------|------|

| | |
|-------------|------|
| upper limit | 1.31 |
|-------------|------|

Notes:

[9] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Secondary: Time to the first occurrence of all-cause death in the subgroup of participants with established CVD at baseline

| | |
|-----------------|--|
| End point title | Time to the first occurrence of all-cause death in the subgroup of participants with established CVD at baseline |
|-----------------|--|

End point description:

Time to the first occurrence of death of any cause in the subgroup of participants with established CVD at baseline

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure | |

| End point values | Epanova | Placebo | | |
|--|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 373 | 333 | | |
| # of participants with events with CVD at baseline | 234 | 202 | | |

Statistical analyses

| | |
|--|-----------------------------|
| Statistical analysis title | Secondary Endpoint Analysis |
| Statistical analysis description: | |
| Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), region and treatment by established CVD at baseline interaction | |
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.091 ^[10] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.97 |
| upper limit | 1.42 |

Notes:

[10] - The hypothesis is tested at the 5% level. A hierarchical test sequence is used to address the issue of multiple testing.

Other pre-specified: Time to emergent/elective coronary revascularization

| | |
|--|--|
| End point title | Time to emergent/elective coronary revascularization |
| End point description: | |
| Time to emergent/elective coronary revascularization | |
| End point type | Other pre-specified |
| End point timeframe: | |
| From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure | |

| End point values | Epanova | Placebo | | |
|------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 414 | 441 | | |

Statistical analyses

| Statistical analysis title | Other Secondary Endpoint Analysis |
|---|-----------------------------------|
| Statistical analysis description: | |
| Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region | |
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.408 ^[11] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.08 |

Notes:

[11] - This endpoint was not in the testing sequence and therefore not under type I error control.

Other pre-specified: Time to hospitalization for unstable angina

| | |
|--|---|
| End point title | Time to hospitalization for unstable angina |
| End point description: | |
| Time to hospitalization for unstable angina | |
| End point type | Other pre-specified |
| End point timeframe: | |
| From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure | |

| End point values | Epanova | Placebo | | |
|------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 87 | 104 | | |

Statistical analyses

| Statistical analysis title | Other Secondary Endpoint Analysis |
|---|-----------------------------------|
| Statistical analysis description: | |
| Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region | |
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.233 ^[12] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.84 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.63 |
| upper limit | 1.12 |

Notes:

[12] - This endpoint was not in the testing sequence and therefore not under type I error control.

Other pre-specified: Time to non-fatal myocardial infarction

| End point title | Time to non-fatal myocardial infarction |
|--|---|
| End point description: | |
| Time to non-fatal myocardial infarction | |
| End point type | Other pre-specified |
| End point timeframe: | |
| From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure | |

| End point values | Epanova | Placebo | | |
|------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 218 | 226 | | |

Statistical analyses

| Statistical analysis title | Other Secondary Endpoint Analysis |
|--|-----------------------------------|
| Statistical analysis description: Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region | |
| Comparison groups | Epanova v Placebo |
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.77 ^[13] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.97 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.17 |

Notes:

[13] - This endpoint was not in the testing sequence and therefore not under type I error control.

Other pre-specified: Time to non-fatal stroke

| | |
|--|--------------------------|
| End point title | Time to non-fatal stroke |
| End point description: Time to non-fatal stroke | |
| End point type | Other pre-specified |
| End point timeframe: From the date of randomization and up to completion of the end-of-treatment visit (Month 60) or at study closure | |

| End point values | Epanova | Placebo | | |
|------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6539 | 6539 | | |
| Units: Participants | | | | |
| Number of participants with events | 142 | 125 | | |

Statistical analyses

| Statistical analysis title | Other Secondary Endpoint Analysis |
|--|-----------------------------------|
| Statistical analysis description: Cox proportional hazards model of time from randomization to the first event as a function of treatment, established CVD at baseline (yes vs. no), and region | |
| Comparison groups | Epanova v Placebo |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 13078 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.278 ^[14] |
| Method | Regression, Cox |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.45 |

Notes:

[14] - This endpoint was not in the testing sequence and therefore not under type I error control.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events will be recorded at all visits for the patients who prematurely discontinue IP. Non Serious Adverse Events will be collected until the final visit but no more than 30 days after the last dose of IP.

Adverse event reporting additional description:

Only Adverse Events that are considered serious, lead to discontinuation of IP or result in a dose modification, overdose, new onset of diabetes mellitus, TIA, PHL cases or bleeding related events will be captured starting after randomization through the final visit.

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 22.1 |

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | Epanova |
|-----------------------|---------|

Reporting group description: -

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

Reporting group description: -

| Serious adverse events | Epanova | Placebo | |
|---|----------------------|----------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2259 / 6532 (34.58%) | 2195 / 6535 (33.59%) | |
| number of deaths (all causes) | 371 | 333 | |
| number of deaths resulting from adverse events | 334 | 299 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acoustic neuroma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute lymphocytic leukaemia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |

| | | | |
|--|------------------|------------------|--|
| Acute promyelocytic leukaemia subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma gastric subjects affected / exposed | 3 / 6532 (0.05%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Adenocarcinoma of colon subjects affected / exposed | 4 / 6532 (0.06%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Adenocarcinoma pancreas subjects affected / exposed | 4 / 6532 (0.06%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Adrenal adenoma subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal cancer subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiomyolipoma subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anogenital warts subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| B-cell prolymphocytic leukaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| B-cell small lymphocytic lymphoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 15 / 6532 (0.23%) | 17 / 6535 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 15 | 1 / 22 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign bone neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of adrenal gland | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of bladder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of eyelid | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign neoplasm of thyroid gland | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign ovarian tumour | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign pancreatic neoplasm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct cancer | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Bladder cancer | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer recurrent | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder squamous cell carcinoma stage unspecified | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 3 / 6532 (0.05%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Bladder transitional cell carcinoma recurrent | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bowen's disease | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain cancer metastatic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm malignant | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 17 / 6535 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Breast cancer female | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Breast cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial carcinoma | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 2 | 0 / 1 | |
| Bronchioloalveolar carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carcinoid tumour pulmonary | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac neoplasm malignant | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Castleman's disease | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervix carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangiocarcinoma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clear cell renal cell carcinoma | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon adenoma | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 10 / 6532 (0.15%) | 20 / 6535 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 6 | |
| Colon cancer metastatic | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Colon cancer stage 0 | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon neoplasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 5 / 6532 (0.08%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Colorectal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colorectal cancer metastatic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Craniopharyngioma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial adenocarcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial cancer | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Essential thrombocythaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Female reproductive neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder cancer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric adenoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Gastrointestinal carcinoma | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastrointestinal stromal tumour | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma multiforme | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemangioma of bone | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head and neck cancer metastatic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cancer | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 4 | |
| Hepatic neoplasm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular carcinoma | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Intestinal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal papillary mucinous neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal papilloma of breast | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraductal proliferative breast lesion | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive breast carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Keratinising squamous cell carcinoma of nasopharynx | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine benign neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal cancer | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Laryngeal neoplasm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lentigo maligna | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lipoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 3 | |
| Lung adenocarcinoma recurrent | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung cancer metastatic | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 7 | |
| Lymphoma | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 11 / 6532 (0.17%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Malignant neoplasm of eye | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant neoplasm of renal pelvis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant neoplasm of spinal cord | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant pleural effusion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant polyp | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mantle cell lymphoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma benign | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to bone | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Metastases to liver | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Metastases to lung | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Metastases to lymph nodes | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastases to peritoneum | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastases to pleura | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to rectum | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to soft tissue | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastasis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic gastric cancer | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic malignant melanoma | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metastatic neoplasm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Metastatic squamous cell carcinoma | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metastatic uterine cancer | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Mucoepidermoid carcinoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelodysplastic syndrome | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelofibrosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Neoplasm malignant | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 3 | |
| Neoplasm of appendix | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm prostate | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm skin | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Neuroendocrine carcinoma metastatic | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma of the skin | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine tumour | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodular melanoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer metastatic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal adenocarcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 6532 (0.05%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal cancer metastatic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal carcinoma | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 0 | |
| Oesophageal papilloma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal cancer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ovarian adenoma | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cancer | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian endometrioid carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian granulosa cell tumour | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paget's disease of the vulva | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic carcinoma | | | |
| subjects affected / exposed | 12 / 6532 (0.18%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 6 | 0 / 3 | |
| Pancreatic carcinoma metastatic | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 2 | |
| Papillary renal cell carcinoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papillary thyroid cancer | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parathyroid tumour benign | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pituitary tumour benign | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Plasma cell myeloma | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasmacytoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 34 / 6532 (0.52%) | 33 / 6535 (0.50%) | |
| occurrences causally related to treatment / all | 0 / 34 | 0 / 34 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Prostate cancer metastatic | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Prostate cancer recurrent | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic adenoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Queyrat erythroplasia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Rectal cancer | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer metastatic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Rectal neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectosigmoid cancer | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland adenoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schwannoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Secretory adenoma of pituitary | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinonasal papilloma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin cancer | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small cell lung cancer | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Small cell lung cancer metastatic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Small intestine carcinoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spindle cell sarcoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Squamous cell carcinoma of lung | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the oral cavity | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the tongue | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Superficial spreading melanoma stage unspecified | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| T-cell lymphoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid adenoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid cancer | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid cancer metastatic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue neoplasm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tongue neoplasm malignant stage unspecified | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric cancer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract neoplasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal adenocarcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer stage I, with cancer in situ | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 I | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 II | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer stage IV | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diffuse large B-cell lymphoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung carcinoma cell type unspecified stage II | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Lung carcinoma cell type unspecified stage IV | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Malignant melanoma stage IV | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Non-Hodgkin's lymphoma | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Non-Hodgkin's lymphoma stage I | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer stage IIIA | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer stage IV | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic carcinoma stage IV | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Prostate cancer stage IV | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer stage IV | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal cell carcinoma stage IV | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Renal cancer stage I | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aneurysm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 16 / 6532 (0.24%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Aortic aneurysm rupture | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic dissection | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Aortic embolus | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stenosis | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure inadequately controlled | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Circulatory collapse | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 14 / 6532 (0.21%) | 15 / 6535 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 15 | 1 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic vascular disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dry gangrene | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism venous | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral artery perforation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemodynamic instability | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 30 / 6532 (0.46%) | 31 / 6535 (0.47%) | |
| occurrences causally related to treatment / all | 2 / 33 | 1 / 35 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 15 / 6532 (0.23%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive urgency | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 11 / 6532 (0.17%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemic shock | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Iliac artery occlusion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iliac artery stenosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inferior vena cava perforation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermittent claudication | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jugular vein thrombosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leriche syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoedema | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant hypertension | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurogenic shock | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic hypotension | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 6532 (0.06%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 30 / 6532 (0.46%) | 45 / 6535 (0.69%) | |
| occurrences causally related to treatment / all | 2 / 39 | 0 / 52 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Peripheral artery aneurysm | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery aneurysm rupture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral coldness | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral ischaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 16 / 6532 (0.24%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 2 / 21 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 13 / 6532 (0.20%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 20 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral venous disease | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phlebitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian artery stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian steal syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vasculitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Hospitalisation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Adverse drug reaction | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adverse event | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-------------------|-------------------|--|
| Cardiac death | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 3 | |
| Catheter site haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 10 / 6532 (0.15%) | 23 / 6535 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complication associated with device | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyst | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 57 / 6532 (0.87%) | 38 / 6535 (0.58%) | |
| occurrences causally related to treatment / all | 4 / 57 | 4 / 38 | |
| deaths causally related to treatment / all | 4 / 57 | 4 / 38 | |
| Decreased activity | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related thrombosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drowning | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Drug intolerance | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exercise tolerance decreased | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General physical health deterioration | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired healing | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site haematoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site inflammation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injection site phlebitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site haematoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mucosal inflammation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multi-organ disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 1 | |
| No adverse event | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodule | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 51 / 6532 (0.78%) | 51 / 6535 (0.78%) | |
| occurrences causally related to treatment / all | 2 / 69 | 0 / 53 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Organ failure | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic mass | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perforation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retention cyst | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stent-graft endoleak | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| 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 | 5 / 6532 (0.08%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 4 | |
| Sudden death | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 1 / 4 | 0 / 3 | |
| Surgical failure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic inflammatory response syndrome | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Unevaluable event | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent occlusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent stenosis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular stent thrombosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic shock | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contrast media allergy | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart transplant rejection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney transplant rejection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sarcoidosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Aborted pregnancy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | | | |

| | | | |
|---|-------------------|-------------------|--|
| Acquired hydrocele | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenomyosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adnexal torsion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 11 / 6532 (0.17%) | 18 / 6535 (0.28%) | |
| occurrences causally related to treatment / all | 1 / 13 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast discharge | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast hyperplasia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast mass | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast pain | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial thickening | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometriosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymal cyst | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Female genital tract fistula | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genital leukoplakia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic ovarian cyst | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic congestion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fluid collection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic prolapse | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perineal cyst | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peyronie's disease | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postmenopausal haemorrhage | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatomegaly | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seminal vesiculitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spermatocele | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular cyst | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular mass | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine polyp | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine prolapse | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal fistula | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal prolapse | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute pulmonary oedema | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 23 / 6532 (0.35%) | 15 / 6535 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 29 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 1 | |
| Asphyxia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Aspiration | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 8 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiectasis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis chronic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchospasm | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 31 / 6532 (0.47%) | 38 / 6535 (0.58%) | |
| occurrences causally related to treatment / all | 0 / 35 | 0 / 42 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic respiratory failure | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chylothorax | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (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 | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphonia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 11 / 6532 (0.17%) | 15 / 6535 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysema | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiglottic cyst | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 13 / 6532 (0.20%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 13 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercapnia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity pneumonitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoxia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal oedema | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngospasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal septum deviation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Organising pneumonia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal stenosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pickwickian syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia aspiration | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 6532 (0.09%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary congestion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 23 / 6532 (0.35%) | 20 / 6535 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 23 | 0 / 20 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | |
| Pulmonary haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary hypertension | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Pulmonary infarction | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Respiratory arrest | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 5 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillar disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord polyp | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Acute psychosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Borderline personality disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Completed suicide | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Confusional state | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conversion disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delirium | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |
| subjects affected / exposed | 10 / 6532 (0.15%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression suicidal | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Insomnia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 6 / 6532 (0.09%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mania | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mood disorder due to a general medical condition | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Organic brain syndrome | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizophrenia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device dislocation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device failure | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device occlusion | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device power source issue | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis in device | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Bile duct stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stone | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 6 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary tract disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis acute | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 13 / 6532 (0.20%) | 17 / 6535 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cholecystitis acute | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 20 / 6532 (0.31%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 2 / 20 | 3 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis chronic | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 27 / 6532 (0.41%) | 15 / 6535 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 28 | 1 / 16 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Chronic hepatitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cirrhosis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Hepatic failure | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hepatic steatosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperbilirubinaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic hepatitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-alcoholic steatohepatitis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nonalcoholic fatty liver disease | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Portal vein thrombosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post cholecystectomy syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anticoagulation drug level above therapeutic | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anticoagulation drug level increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood calcium decreased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Blood glucose abnormal subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose decreased subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose fluctuation subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose increased subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood lactic acid increased subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| C-reactive protein increased subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrocardiogram change | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glycosylated haemoglobin increased | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intraocular pressure increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatic specific antigen increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus rhythm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transaminases increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transplant evaluation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trial of void | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin increased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight increased | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Troponin I increased | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Abdominal injury | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental overdose | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acetabulum fracture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Airway complication of anaesthesia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol poisoning | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial bypass occlusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial bypass stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back injury | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone contusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain contusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns second degree | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbon monoxide poisoning | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery restenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical vertebral fracture | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Chest injury | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery restenosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocerebral injury | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cystitis radiation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epicondylitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eyelid injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial bones fracture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 15 / 6532 (0.23%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Femur fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 8 / 6532 (0.12%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Forearm fracture | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body aspiration | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body in gastrointestinal tract | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture displacement | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Frostbite | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head injury | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hip fracture | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Hyphaema | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammation of wound | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Intentional overdose | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament rupture | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb traumatic amputation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mallet finger | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple fractures | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple injuries | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle rupture | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle strain | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck injury | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Overdose | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Patella fracture | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic organ injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery restenosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral nerve injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periprosthetic fracture | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal contusion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Poisoning | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Post concussion syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post laminectomy syndrome | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural fever | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematuria | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural swelling | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative delirium | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative hypotension | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative ileus | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative respiratory failure | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative thoracic procedure complication | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural hypotension | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural nausea | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudomeningocele | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pubis fracture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiation dysphagia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiation injury | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 7 / 6532 (0.11%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Road traffic accident | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Scapula fracture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shunt thrombosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skeletal injury | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin laceration | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fracture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skull fractured base | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue injury | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal compression fracture | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic rupture | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous haematoma | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 11 / 6532 (0.17%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suture related complication | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon injury | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal burn | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic arthrosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haematoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haemothorax | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic ulcer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulna fracture | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral injury | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular graft occlusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular procedure complication | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Arteriovenous malformation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial septal defect | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular arteriovenous malformation | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Familial mediterranean fever | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic cardiomyopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phimosis | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Porokeratosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyloric stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 13 / 6532 (0.20%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 2 | |
| Acute left ventricular failure | | | |

| | | | |
|---|--------------------|--------------------|--|
| subjects affected / exposed | 16 / 6532 (0.24%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 40 / 6532 (0.61%) | 45 / 6535 (0.69%) | |
| occurrences causally related to treatment / all | 0 / 53 | 1 / 47 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 6 | |
| Angina pectoris | | | |
| subjects affected / exposed | 92 / 6532 (1.41%) | 102 / 6535 (1.56%) | |
| occurrences causally related to treatment / all | 1 / 110 | 0 / 113 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |
| subjects affected / exposed | 112 / 6532 (1.71%) | 141 / 6535 (2.16%) | |
| occurrences causally related to treatment / all | 7 / 125 | 19 / 162 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Anginal equivalent | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve disease | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve incompetence | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 12 / 6532 (0.18%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 12 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 19 / 6532 (0.29%) | 15 / 6535 (0.23%) | |
| occurrences causally related to treatment / all | 6 / 23 | 3 / 20 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Arteriospasm coronary | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 150 / 6532 (2.30%) | 89 / 6535 (1.36%) | |
| occurrences causally related to treatment / all | 2 / 188 | 2 / 103 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Atrial flutter | | | |
| subjects affected / exposed | 14 / 6532 (0.21%) | 17 / 6535 (0.26%) | |
| occurrences causally related to treatment / all | 1 / 20 | 1 / 20 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial tachycardia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block first degree | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block second degree | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular dissociation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradyarrhythmia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac aneurysm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 19 / 6532 (0.29%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 11 | 0 / 9 | |
| Cardiac asthma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac discomfort | | | |

| | | |
|---|-------------------|-------------------|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) |
| 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 | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardiac failure | | |
| subjects affected / exposed | 90 / 6532 (1.38%) | 92 / 6535 (1.41%) |
| occurrences causally related to treatment / all | 0 / 117 | 10 / 132 |
| deaths causally related to treatment / all | 0 / 12 | 0 / 12 |
| Cardiac failure acute | | |
| subjects affected / exposed | 27 / 6532 (0.41%) | 21 / 6535 (0.32%) |
| occurrences causally related to treatment / all | 0 / 35 | 0 / 25 |
| deaths causally related to treatment / all | 0 / 4 | 0 / 5 |
| Cardiac failure chronic | | |
| subjects affected / exposed | 18 / 6532 (0.28%) | 21 / 6535 (0.32%) |
| occurrences causally related to treatment / all | 0 / 21 | 2 / 26 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 |
| Cardiac failure congestive | | |
| subjects affected / exposed | 60 / 6532 (0.92%) | 59 / 6535 (0.90%) |
| occurrences causally related to treatment / all | 0 / 83 | 0 / 77 |
| deaths causally related to treatment / all | 0 / 9 | 0 / 9 |
| Cardiac tamponade | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardiac ventricular thrombosis | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cardio-respiratory arrest | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cardio-respiratory distress | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiogenic shock | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 1 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiopulmonary failure | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 5 | |
| Cardiovascular deconditioning | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiovascular insufficiency | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congestive cardiomyopathy | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 82 / 6532 (1.26%) | 61 / 6535 (0.93%) | |
| occurrences causally related to treatment / all | 10 / 89 | 19 / 72 | |
| deaths causally related to treatment / all | 0 / 7 | 0 / 2 | |
| Coronary artery insufficiency | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery stenosis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery thrombosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diastolic dysfunction | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extrasystoles | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive heart disease | | | |

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|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracardiac thrombus | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 4 / 6532 (0.06%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Left ventricular dysfunction | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Left ventricular failure | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Metabolic cardiomyopathy | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve disease | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial fibrosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 39 / 6532 (0.60%) | 51 / 6535 (0.78%) | |
| occurrences causally related to treatment / all | 0 / 43 | 1 / 51 | |
| deaths causally related to treatment / all | 0 / 10 | 1 / 22 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 27 / 6532 (0.41%) | 16 / 6535 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 28 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 6 | 0 / 2 | |
| Myocarditis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodal arrhythmia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nodal rhythm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paroxysmal atrioventricular block | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| 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 | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuropericarditis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postinfarction angina | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary valve stenosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulseless electrical activity | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Right ventricular failure | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Silent myocardial infarction | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinoatrial block | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus arrest | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus bradycardia | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular extrasystoles | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachyarrhythmia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachycardia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular arrhythmia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular dysfunction | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 5 | 2 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular fibrillation | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 13 / 6532 (0.20%) | 14 / 6535 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adams-Stokes syndrome | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amnesia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amyotrophic lateral sclerosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Aphasia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autonomic nervous system imbalance | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal ganglia infarction | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basilar artery aneurysm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basilar artery stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain stem ischaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain stem stroke | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid arteriosclerosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery disease | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |
| subjects affected / exposed | 17 / 6532 (0.26%) | 14 / 6535 (0.21%) | |
| occurrences causally related to treatment / all | 1 / 18 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar stroke | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral artery stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haematoma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cerebral infarction | | | |
| subjects affected / exposed | 12 / 6532 (0.18%) | 17 / 6535 (0.26%) | |
| occurrences causally related to treatment / all | 2 / 12 | 7 / 18 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 6 | 2 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cerebral small vessel ischaemic disease | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral venous sinus thrombosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cerebrovascular accident | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 45 / 6532 (0.69%) | 42 / 6535 (0.64%) | |
| occurrences causally related to treatment / all | 0 / 46 | 0 / 43 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 12 | |
| Cerebrovascular insufficiency | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 2 / 4 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cerebrovascular stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical radiculopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervicobrachial syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cluster headache | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cognitive disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Demyelination | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic autonomic neuropathy | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic coma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diabetic neuropathy | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness postural | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Encephalopathy | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Essential tremor | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paralysis | | | |
| subjects affected / exposed | 10 / 6532 (0.15%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 1 / 10 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paresis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised tonic-clonic seizure | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Haemorrhagic stroke | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Haemorrhagic transformation stroke | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive encephalopathy | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotonia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial aneurysm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic cerebral infarction | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 30 / 6532 (0.46%) | 24 / 6535 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 33 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 3 | |
| Lacunar infarction | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 3 | 3 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lacunar stroke | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar radiculopathy | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbosacral plexus lesion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbosacral radiculopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Memory impairment | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental impairment | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monoplegia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple sclerosis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Multiple sclerosis relapse | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myasthenia gravis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myoclonus | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve compression | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuralgia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurological symptom | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.02%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normal pressure hydrocephalus | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraparesis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraplegia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinson's disease | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parkinsonism | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Posterior reversible encephalopathy syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 8 / 6532 (0.12%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radial nerve palsy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radicular pain | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radiculopathy | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord compression | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord haematoma | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord herniation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord infarction | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal cord ischaemia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal vascular disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylitic myelopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 5 / 6532 (0.08%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 32 / 6532 (0.49%) | 15 / 6535 (0.23%) | |
| occurrences causally related to treatment / all | 1 / 33 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thalamic infarction | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient aphasia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient global amnesia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 41 / 6532 (0.63%) | 41 / 6535 (0.63%) | |
| occurrences causally related to treatment / all | 1 / 46 | 4 / 45 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tremor | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular dementia | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Vascular encephalopathy | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular headache | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar insufficiency | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 4 / 6532 (0.06%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebrobasilar stroke | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord paralysis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dementia Alzheimer's type | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IIIrd nerve paralysis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Agranulocytosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia | | | |
| subjects affected / exposed | 15 / 6532 (0.23%) | 19 / 6535 (0.29%) | |
| occurrences causally related to treatment / all | 2 / 17 | 0 / 25 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia macrocytic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Antiphospholipid syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood loss anaemia | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulopathy | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disseminated intravascular coagulation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 9 / 6532 (0.14%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 1 / 10 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microcytic anaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrogenic anaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normocytic anaemia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polycythaemia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic infarction | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic thrombosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenomegaly | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Deafness | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deafness unilateral | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoacusis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otolithiasis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden hearing loss | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tinnitus | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 12 / 6532 (0.18%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 1 / 13 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 29 / 6532 (0.44%) | 20 / 6535 (0.31%) | |
| occurrences causally related to treatment / all | 1 / 35 | 2 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conjunctival erosion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conjunctivochalasis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Corneal erosion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dacryostenosis acquired | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic retinopathy | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diplopia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exophthalmos | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eyelid ptosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glaucoma | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iridocyclitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular hole | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Maculopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Open angle glaucoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Optic ischaemic neuropathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal artery embolism | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal artery occlusion | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal detachment | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal tear | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal vein occlusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhegmatogenous retinal detachment | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tractional retinal detachment | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous detachment | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal distension | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 5 / 6532 (0.08%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia obstructive | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholic pancreatitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fistula | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal stenosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anogenital dysplasia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic gastritis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 3 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coeliac artery stenosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 7 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic fistula | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dental cyst | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gastroparesis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gastropathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diaphragmatic hernia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 21 / 6532 (0.32%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 9 / 21 | 5 / 11 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Dieulafoy's vascular malformation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal perforation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal polyp | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Duodenal ulcer perforation | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenogastric reflux | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysbiosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterovesical fistula | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erosive duodenitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Functional gastrointestinal disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastric polyps | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer perforation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastritis | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis erosive | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 6532 (0.09%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis haemorrhagic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroduodenal ulcer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorder | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal erosion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 24 / 6532 (0.37%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 1 / 31 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Gastrointestinal inflammation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal polyp haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal vascular malformation haemorrhagic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gingival bleeding | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic erosive gastritis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoidal haemorrhage | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiatus hernia | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus paralytic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated inguinal hernia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 18 / 6532 (0.28%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal haemorrhage | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Intestinal ischaemia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Intestinal mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal polyp | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal pseudo-obstruction | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-abdominal haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine perforation | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 14 / 6532 (0.21%) | 13 / 6535 (0.20%) | |
| occurrences causally related to treatment / all | 1 / 15 | 2 / 19 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mechanical ileus | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric artery stenosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mesenteric vascular insufficiency | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Mouth haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Noninfective sialoadenitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive pancreatitis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedematous pancreatitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal achalasia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal spasm | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal stenosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal varices haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic disorder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 11 / 6532 (0.17%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 1 / 11 | 1 / 10 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 1 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 12 / 6532 (0.18%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 3 / 16 | 3 / 11 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Pancreatitis chronic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngo-oesophageal diverticulum | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumatosis intestinalis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal polyp | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal prolapse | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reflux gastritis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal fibrosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haematoma | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Retroperitoneal mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 5 / 6532 (0.08%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis mesenteric vessel | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Tongue cyst | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 5 / 6532 (0.08%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 12 / 6532 (0.18%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 12 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Volvulus | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Volvulus of small bowel | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Acanthosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alopecia scarring | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angioedema | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatomyositis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Diabetic foot | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 14 / 6535 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eczema | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erythema multiforme | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granuloma annulare | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity vasculitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic skin ulcer | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Panniculitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin necrosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin ulcer | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 8 / 6532 (0.12%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urticaria | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Henoch-Schonlein purpura | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 46 / 6532 (0.70%) | 53 / 6535 (0.81%) | |
| occurrences causally related to treatment / all | 0 / 54 | 0 / 59 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 3 | |
| Azotaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Bladder mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder outlet obstruction | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder prolapse | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus urinary | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 15 / 6532 (0.23%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic nephropathy | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End stage renal disease | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Genitourinary symptom | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 8 / 6532 (0.12%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive nephropathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertonic bladder | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ketonuria | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower urinary tract symptoms | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 15 / 6532 (0.23%) | 20 / 6535 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrotic syndrome | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal artery arteriosclerosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal artery stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal artery thrombosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal embolism | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 17 / 6532 (0.26%) | 16 / 6535 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 17 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 3 | |
| Renal haematoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal haemorrhage | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Renal injury | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal ischaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal mass | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stag horn calculus | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress urinary incontinence | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial nephritis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric stenosis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary bladder haemorrhage | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary fistula | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 6 / 6532 (0.09%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Acromegaly | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adrenal mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Goitre | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperparathyroidism primary | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parathyroid disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid mass | | | |

| | | | |
|--|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | | | |
| Arthralgia | | | |
| subjects affected / exposed | 10 / 6532 (0.15%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 10 | 1 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone lesion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical spinal stenosis | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis pyrophosphate | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Compartment syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costochondritis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crystal arthropathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibromyalgia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Flank pain | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| 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 | 4 / 6532 (0.06%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture nonunion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gouty arthritis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin pain | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma muscle | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc displacement | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 13 / 6532 (0.20%) | 17 / 6535 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 13 | 1 / 17 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Joint ankylosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint effusion | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb deformity | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb discomfort | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb mass | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 18 / 6532 (0.28%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mandibular mass | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscal degeneration | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mobility decreased | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myalgia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck pain | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathic arthropathy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 66 / 6532 (1.01%) | 58 / 6535 (0.89%) | |
| occurrences causally related to treatment / all | 0 / 69 | 0 / 67 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondrosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis of jaw | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoporosis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periarthritis | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polymyalgia rheumatica | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatic disorder | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal instability | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 17 / 6532 (0.26%) | 8 / 6535 (0.12%) | |
| occurrences causally related to treatment / all | 2 / 17 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal pain | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal stenosis | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 11 / 6535 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolysis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tenosynovitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic spinal stenosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral foraminal stenosis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall abscess | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 4 / 6532 (0.06%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acarodermatitis | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acquired immunodeficiency syndrome | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute sinusitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenovirus infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 14 / 6535 (0.21%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis perforated | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis infective | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial colitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial prostatitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary sepsis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Borrelia infection | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast abscess | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 10 / 6532 (0.15%) | 23 / 6535 (0.35%) | |
| occurrences causally related to treatment / all | 0 / 11 | 2 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis infective | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Campylobacter colitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Candida pneumonia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbuncle | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 39 / 6532 (0.60%) | 46 / 6535 (0.70%) | |
| occurrences causally related to treatment / all | 1 / 46 | 0 / 52 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis of male external genital organ | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis staphylococcal | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest wall abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis infective | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 2 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile colitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis infected | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diabetic foot infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic gangrene | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea infectious | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 13 / 6532 (0.20%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis intestinal haemorrhagic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysentery | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Emphysematous pyelonephritis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Empyema | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis bacterial | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterococcal sepsis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epidemic pleurodynia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 10 | 2 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia pyelonephritis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia sepsis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia urinary tract infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| External ear cellulitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fournier's gangrene | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Fungal infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder empyema | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastroenteritis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 15 / 6532 (0.23%) | 20 / 6535 (0.31%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 20 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis clostridial | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal viral infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genitourinary tract infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Groin abscess | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helicobacter gastritis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cyst infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Implant site infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site cellulitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected cyst | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected dermal cyst | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected skin ulcer | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious pleural effusion | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective aneurysm | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective exacerbation of chronic obstructive airways disease | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective tenosynovitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 12 / 6532 (0.18%) | 15 / 6535 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral discitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal gangrene | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Klebsiella infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 5 / 6535 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 1 | 2 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection bacterial | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lyme disease | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphangitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinitis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site abscess | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical device site joint infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis bacterial | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Meningoencephalitis herpetic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Moraxella infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mycetoma mycotic | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotising fasciitis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal candidiasis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis acute | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis chronic | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media acute | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media bacterial | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media chronic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parotitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perineal abscess | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periodontitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perirectal abscess | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonsillitis | | | |

| | | |
|---|--------------------|--------------------|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Pilonidal cyst | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Pneumonia | | |
| subjects affected / exposed | 113 / 6532 (1.73%) | 126 / 6535 (1.93%) |
| occurrences causally related to treatment / all | 5 / 130 | 3 / 135 |
| deaths causally related to treatment / all | 1 / 11 | 0 / 14 |
| Pneumonia bacterial | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Pneumonia haemophilus | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Pneumonia legionella | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 |
| Pneumonia pseudomonal | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Pneumonia staphylococcal | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Pneumonia streptococcal | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (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 | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural cellulitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural sepsis | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Postoperative abscess | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudomonas infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psoas abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary nocardiosis | | | |

| | | | |
|---|------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 9 / 6532 (0.14%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 7 / 6532 (0.11%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 9 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis chronic | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salmonellosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal abscess | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 49 / 6532 (0.75%) | 43 / 6535 (0.66%) | |
| occurrences causally related to treatment / all | 0 / 51 | 0 / 47 | |
| deaths causally related to treatment / all | 0 / 8 | 0 / 11 | |
| Septic necrosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 3 | |
| Sinobronchitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (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 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal abscess | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| 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 | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 4 / 6535 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal sepsis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth abscess | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| 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 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 1 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 24 / 6532 (0.37%) | 36 / 6535 (0.55%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 40 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Urosepsis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 9 / 6532 (0.14%) | 9 / 6535 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Vestibular neuronitis | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection bacterial | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound sepsis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute hepatitis B | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HIV infection | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis C | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Cardiometabolic syndrome | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Central obesity | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |
| subjects affected / exposed | 8 / 6532 (0.12%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 43 / 6532 (0.66%) | 49 / 6535 (0.75%) | |
| occurrences causally related to treatment / all | 4 / 47 | 7 / 50 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Diabetes mellitus inadequate control | | | |
| subjects affected / exposed | 26 / 6532 (0.40%) | 24 / 6535 (0.37%) | |
| occurrences causally related to treatment / all | 2 / 29 | 3 / 32 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic complication | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 6532 (0.09%) | 6 / 6535 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Diabetic ketosis | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Diabetic metabolic decompensation | | | |
| subjects affected / exposed | 16 / 6532 (0.24%) | 13 / 6535 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid overload | | | |
| subjects affected / exposed | 3 / 6532 (0.05%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gout | | | |
| subjects affected / exposed | 6 / 6532 (0.09%) | 7 / 6535 (0.11%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 13 / 6532 (0.20%) | 12 / 6535 (0.18%) | |
| occurrences causally related to treatment / all | 1 / 13 | 1 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperhomocysteinaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 5 / 6532 (0.08%) | 13 / 6535 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 5 | 1 / 13 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypervolaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 2 / 6535 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 14 / 6532 (0.21%) | 16 / 6535 (0.24%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 18 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6532 (0.03%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 3 / 6535 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 4 / 6532 (0.06%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ketoacidosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lactic acidosis | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 6532 (0.00%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 2 / 6532 (0.03%) | 1 / 6535 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Obesity | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 6 / 6532 (0.09%) | 10 / 6535 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 28 / 6532 (0.43%) | 18 / 6535 (0.28%) | |
| occurrences causally related to treatment / all | 4 / 32 | 1 / 19 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 1 / 6532 (0.02%) | 0 / 6535 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events | Epanova | Placebo | |
|---|----------------------|---------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1689 / 6532 (25.86%) | 964 / 6535 (14.75%) | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 87 / 6532 (1.33%) | 35 / 6535 (0.54%) | |
| occurrences (all) | 102 | 38 | |
| Abdominal pain | | | |
| subjects affected / exposed | 90 / 6532 (1.38%) | 54 / 6535 (0.83%) | |
| occurrences (all) | 104 | 61 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 80 / 6532 (1.22%) | 59 / 6535 (0.90%) | |
| occurrences (all) | 99 | 68 | |
| Diarrhoea | | | |
| subjects affected / exposed | 765 / 6532 (11.71%) | 316 / 6535 (4.84%) | |
| occurrences (all) | 1049 | 386 | |
| Dyspepsia | | | |
| subjects affected / exposed | 89 / 6532 (1.36%) | 41 / 6535 (0.63%) | |
| occurrences (all) | 104 | 53 | |
| Nausea | | | |

| | | | |
|---|---------------------------|---------------------------|--|
| subjects affected / exposed occurrences (all) | 204 / 6532 (3.12%) 229 | 110 / 6535 (1.68%) 126 | |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 97 / 6532 (1.48%) 193 | 75 / 6535 (1.15%) 145 | |
| Metabolism and nutrition disorders Diabetes mellitus subjects affected / exposed occurrences (all) | 147 / 6532 (2.25%) 150 | 121 / 6535 (1.85%) 122 | |
| Type 2 diabetes mellitus subjects affected / exposed occurrences (all) | 130 / 6532 (1.99%) 131 | 153 / 6535 (2.34%) 155 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 23 July 2014 | To enrich CV risk in the study population by adding low HDL-C criterion. Additions based on FDA recommendations. Low HDL inclusion criterion added: HDL-C <40 mg/dL (1.03 mmol/L) for men or HDL-C <45 mg/dL (1.16 mmol/L) for women. Added FDA recommendations from SPA: 1) Impaired renal function change from MDRD to CKD-EPI formula, 2) High-intensity statin treatment clarified specifically as atorvastatin 40 or 80 mg and rosuvastatin 20 or 40 mg, 3) Added exclusion criterion of known hypersensitivity to fish and/or shellfish. ITT and safety population analysis sets clarified. Added interim analyses. Removed sample size re-estimation. Clarified time to CV death as the third key secondary endpoint. TIA added as an AE to the predefined list of selective AEs for collection. |
| 09 September 2014 | Allow for enhanced recruitment without changing CV risk profile substantially. Clarified key secondary endpoint throughout the CSP. Food questionnaire removed. Biobank samples changed to include US patients only. Number of lipid markers were reduced. |
| 30 May 2015 | Allow for enhanced recruitment without changing CV risk profile substantially. Thresholds for TG and HDL-C changed from TG ≥ 200 and <500 mg/dL and HDL-C <40 mg/dL for males or <45 mg/dL for female to TG ≥ 180 and <500 mg/dL and HDL-C <42 mg/dL for males, <47 mg/dL for females. First key secondary outcome measure changed from composite of CV death, non-fatal MI, non-fatal stroke to composite of cardiac death, non-fatal MI and non-fatal stroke. Other clarifications: Carotid stenting added as established atherosclerotic CVD. Definition of family history of premature CHD clarified. Niacin dose clarified. HbA1c exclusion criterion changed from >10% to >12% at visit 1. Clarified use of omega-3 dietary supplements. Clarified time windows for selected exclusion criteria. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported