



Clinical trial results:

A Randomized, Double-blind, Phase 3 Trial to Assess Clinical Efficacy, Safety and Reactogenicity of the Recombinant MVA-BN®-RSV Vaccine in Adults 60 Years of Age

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2021-004923-34 |
| Trial protocol | DE |
| Global end of trial date | 10 October 2023 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 14 September 2024 |
| First version publication date | 14 September 2024 |
| Summary attachment (see zip file) | Summary of Secondary Safety Endpoints (RSV-MVA-004 Summary of Secondary Safety Endpoints.pdf) |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | RSV-MVA-004 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05238025 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Bavarian Nordic A/S |
| Sponsor organisation address | Philip Heymans Alle 3, Hellerup, Denmark, 2900 |
| Public contact | clinical-mailbox , Bavarian Nordic GmbH, clinical-mailbox@bavarian-nordic.com |
| Scientific contact | clinical-mailbox , Bavarian Nordic GmbH, clinical-mailbox@bavarian-nordic.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 | 10 October 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 29 June 2023 |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 October 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

To assess the clinical efficacy of MVA-BN-RSV vaccine against lower respiratory tract disease (LRTD) associated with RSV.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 19 April 2022 |
| 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 | United States: 16913 |
| Country: Number of subjects enrolled | Germany: 1435 |
| Worldwide total number of subjects | 18348 |
| EEA total number of subjects | 1435 |

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) | 1864 |
| From 65 to 84 years | 16122 |
| 85 years and over | 362 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 18367 subjects were randomised, out of which 18348 were vaccinated.

Period 1

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

Arms

| | |
|------------------------------|------------|
| Are arms mutually exclusive? | Yes |
| Arm title | MVA-BN-RSV |

Arm description:

Single administration of MVA-BN-RSV vaccine with a titer of at least 3 x 10E8 infectious units (Inf.U)/0.5mL (intramuscular injection)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | MVA-BN-RSV |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single administration of MVA-BN-RSV vaccine with a titer of at least 3 x 10E8 infectious units (Inf.U)/0.5mL (intramuscular injection)

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

Arm description:

Single administration of Tris-buffered Saline (TBS) (intramuscular injection; 0.5mL)

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

Dosage and administration details:

Single administration of Tris-buffered Saline (TBS) (intramuscular injection; 0.5mL)

| Number of subjects in period 1 | MVA-BN-RSV | Placebo |
|---------------------------------------|------------|---------|
| Started | 9160 | 9188 |
| Completed | 1530 | 1535 |
| Not completed | 7630 | 7653 |
| Adverse event, serious fatal | 38 | 32 |
| Consent withdrawn by subject | 203 | 222 |
| Physician decision | 20 | 8 |
| Study terminated by Sponsor | 6358 | 6358 |
| Adverse event, non-fatal | 2 | 2 |
| Other reason | 669 | 690 |
| Lost to follow-up | 334 | 339 |
| Protocol deviation | 6 | 2 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | MVA-BN-RSV |
|-----------------------|------------|

Reporting group description:

Single administration of MVA-BN-RSV vaccine with a titer of at least 3 x 10E8 infectious units (Inf.U)/0.5mL (intramuscular injection)

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

Reporting group description:

Single administration of Tris-buffered Saline (TBS) (intramuscular injection; 0.5mL)

| Reporting group values | MVA-BN-RSV | Placebo | Total |
|---|------------|---------|-------|
| Number of subjects | 9160 | 9188 | 18348 |
| Age categorical | | | |
| Baseline characteristics data are presented for the Full Analysis Set | | | |
| Units: Subjects | | | |
| 60-64 years | 931 | 933 | 1864 |
| 65-74 years | 6166 | 6164 | 12330 |
| 75-84 years | 1889 | 1903 | 3792 |
| 85 years and over | 174 | 188 | 362 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 70.4 | 70.5 | |
| standard deviation | ± 5.78 | ± 5.83 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 4606 | 4680 | 9286 |
| Male | 4554 | 4508 | 9062 |
| Race | | | |
| Units: Subjects | | | |
| White | 7786 | 7794 | 15580 |
| Black or African American | 1185 | 1202 | 2387 |
| Asian | 79 | 63 | 142 |
| Native Hawaiian or Other Pacific Islander | 9 | 15 | 24 |
| American Indian or Alaska Native | 34 | 26 | 60 |
| Other | 67 | 87 | 154 |
| Not Reported | 0 | 1 | 1 |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 2605 | 2659 | 5264 |
| Not Hispanic or Latino | 6464 | 6432 | 12896 |
| Not Reported | 76 | 87 | 163 |
| Unknown | 15 | 10 | 25 |

End points

End points reporting groups

| | |
|-----------------------|------------|
| Reporting group title | MVA-BN-RSV |
|-----------------------|------------|

Reporting group description:

Single administration of MVA-BN-RSV vaccine with a titer of at least 3×10^8 infectious units (Inf.U)/0.5mL (intramuscular injection)

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

Reporting group description:

Single administration of Tris-buffered Saline (TBS) (intramuscular injection; 0.5mL)

| | |
|----------------------------|-------------------|
| Subject analysis set title | Full Analysis Set |
|----------------------------|-------------------|

| | |
|---------------------------|---------------|
| Subject analysis set type | Full analysis |
|---------------------------|---------------|

Subject analysis set description:

Subjects who were randomised to any treatment arm and received study vaccine (MVA-BN-RSV or placebo). Subjects were analysed based on the treatment to which they were randomised. Subjects who received multiple doses of study vaccine ("multiple enrollers") were included once in this analysis set with group allocation based on their first randomisation and with data censored from the time of second randomisation.

| | |
|----------------------------|------------|
| Subject analysis set title | Safety Set |
|----------------------------|------------|

| | |
|---------------------------|-----------------|
| Subject analysis set type | Safety analysis |
|---------------------------|-----------------|

Subject analysis set description:

Subjects who received study vaccine (MVA-BN-RSV or placebo). Subjects were analysed based on the treatment they actually received. Subjects who received multiple doses of study vaccine ("multiple enrollers") were analysed in the MVA-BN-RSV arm when having received the MVA-BN-RSV vaccine at least once; subjects were analysed in the placebo arm when having received placebo only.

| | |
|----------------------------|-----------------------------|
| Subject analysis set title | Immunogenicity Analysis Set |
|----------------------------|-----------------------------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

Subject analysis set description:

A subset of the Full Analysis Set that includes those subjects at designated clinical trial sites who signed the informed consent form for the collection of serum samples and have at least one immunogenicity sample available

Primary: Occurrence of PCR Confirmed RSV-associated LRTD With at Least 3 Symptoms

| | |
|-----------------|--|
| End point title | Occurrence of PCR Confirmed RSV-associated LRTD With at Least 3 Symptoms |
|-----------------|--|

End point description:

RSV-associated lower respiratory tract disease (LRTD) is defined by the presence of clinical evidence of at least 1 sign or symptom of acute respiratory disease (ARD) and at least 3 LRTD signs or symptoms with onset ≥ 14 days following vaccination until the end of one RSV season (up to 12 months after vaccination), confirmed and documented by a medical professional, together with RSV disease confirmed by polymerase chain reaction (PCR).

Population: Full Analysis Set.

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

End point timeframe:

From 14 days post-vaccination up to the end of one RSV season

| End point values | MVA-BN-RSV | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9160 | 9188 | | |
| Units: Subjects | 12 | 21 | | |

Statistical analyses

| Statistical analysis title | Vaccine Efficacy (%) |
|---|----------------------|
| Statistical analysis description: | |
| Vaccine Efficacy (VE) is defined as 1 minus the hazard ratio resulting from a Cox proportional hazards regression model stratified by age group. It is demonstrated if the lower limit (LL) of the 2-sided 95% confidence interval (CI) for VE is above 20% | |
| Comparison groups | MVA-BN-RSV v Placebo |
| Number of subjects included in analysis | 18348 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Vaccine Efficacy |
| Point estimate | 42.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -16.1 |
| upper limit | 71.9 |

Primary: Occurrence of PCR Confirmed RSV-associated LRTD With at Least 2 Symptoms

| End point title | Occurrence of PCR Confirmed RSV-associated LRTD With at Least 2 Symptoms |
|---|--|
| End point description: | |
| RSV-associated lower respiratory tract disease (LRTD) is defined by the presence of clinical evidence of at least 1 sign or symptom of acute respiratory disease (ARD) and at least 2 LRTD signs or symptoms with onset ≥ 14 days following vaccination until the end of one RSV season (up to 12 months after vaccination), confirmed and documented by a medical professional, together with RSV disease confirmed by polymerase chain reaction (PCR). Population: Full Analysis Set. | |
| End point type | Primary |
| End point timeframe: | |
| From 14 days post-vaccination up to the end of one RSV season | |

| End point values | MVA-BN-RSV | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9160 | 9188 | | |
| Units: Subjects | 25 | 61 | | |

Statistical analyses

| Statistical analysis title | Vaccine Efficacy (%) |
|--|----------------------|
| Statistical analysis description: | |
| Vaccine Efficacy (VE) is defined as 1 minus the hazard ratio resulting from a Cox proportional hazards regression model stratified by age group. It is demonstrated if the first primary outcome is met and the lower limit (LL) of the 2-sided 95% confidence interval (CI) for VE is above 20% | |
| Comparison groups | MVA-BN-RSV v Placebo |
| Number of subjects included in analysis | 18348 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[1] |
| Parameter estimate | Vaccine Efficacy |
| Point estimate | 59 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 34.7 |
| upper limit | 74.3 |

Notes:

[1] - Not formally tested, since the first primary outcome was not met

Secondary: Occurrence of PCR Confirmed RSV-associated ARD

| End point title | Occurrence of PCR Confirmed RSV-associated ARD |
|---|--|
| End point description: | |
| RSV-associated acute respiratory disease (ARD) is defined by the presence of either one ARD symptom lasting for at least 24 hours or two simultaneously occurring ARD symptoms (irrespective of duration), with onset ≥ 14 days following vaccination until the end of one RSV season (up to 12 months after vaccination), confirmed and documented by a medical professional, together with RSV disease confirmed by polymerase chain reaction (PCR). Population: Full Analysis Set. | |
| End point type | Secondary |
| End point timeframe: | |
| From 14 days post-vaccination up to the end of one RSV season | |

| End point values | MVA-BN-RSV | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9160 | 9188 | | |
| Units: Subjects | 42 | 82 | | |

Statistical analyses

| | |
|--|----------------------|
| Statistical analysis title | Vaccine Efficacy (%) |
| Statistical analysis description: Vaccine Efficacy (VE) is defined as 1 minus the hazard ratio resulting from a Cox proportional hazards regression model stratified by age group. It is demonstrated if both primary outcomes are met and the lower limit (LL) of the 2-sided 95% confidence interval (CI) for VE is above 20% | |
| Comparison groups | MVA-BN-RSV v Placebo |
| Number of subjects included in analysis | 18348 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[2] |
| Parameter estimate | Vaccine Efficacy |
| Point estimate | 48.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 25.8 |
| upper limit | 64.7 |

Notes:

[2] - Not formally tested, since the first primary outcome was not met

Secondary: Occurrence of Complications Related to PCR-confirmed RSV Disease

| | |
|-----------------|--|
| End point title | Occurrence of Complications Related to PCR-confirmed RSV Disease |
|-----------------|--|

End point description:

RSV-specific complications include the presence of acute clinical consequences of RSV infection, such as pneumonia (incl. bacterial superinfection), sepsis, positive blood culture, and pneumothorax as well as longer term consequences of RSV-specific symptoms, such as persistent worsening of chronic conditions (e.g. COPD), new onset of persistent medical conditions (e.g. chronically impaired lung function, asthma) or a worsening of the functional status of the patient, e.g. new onset of nursing or assisted living need. RSV disease had to be confirmed by PCR testing.

Population: Full Analysis Set.

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

End point timeframe:

From 14 days post-vaccination up to the end of one RSV season

| | | | | |
|-----------------------------|-----------------|-----------------|--|--|
| End point values | MVA-BN-RSV | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9160 | 9188 | | |
| Units: Subjects | 0 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Occurrence of Hospitalization Due to Confirmed RSV Disease or Due to Any Complication Related to RSV-confirmed Respiratory Disease

| | |
|-----------------|--|
| End point title | Occurrence of Hospitalization Due to Confirmed RSV Disease or Due to Any Complication Related to RSV-confirmed Respiratory |
|-----------------|--|

End point description:

Hospitalization due to PCR confirmed RSV disease and/or any complication related to PCR-confirmed RSV disease. RSV-specific complications include the presence of acute clinical consequences of RSV infection, such as pneumonia (incl. bacterial superinfection), sepsis, positive blood culture, and pneumothorax as well as longer term consequences of RSV-specific symptoms, such as persistent worsening of chronic conditions (e.g. COPD), new onset of persistent medical conditions (e.g. chronically impaired lung function, asthma) or a worsening of the functional status of the patient, e.g. new onset of nursing or assisted living need. RSV disease had to be confirmed by PCR testing.

Population: Full Analysis Set.

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

End point timeframe:

From 14 days post-vaccination up to the end of one RSV season

| End point values | MVA-BN-RSV | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9160 | 9188 | | |
| Units: Subjects | 0 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Occurrence of Severe PCR Confirmed RSV-associated LRTD

| | |
|-----------------|--|
| End point title | Occurrence of Severe PCR Confirmed RSV-associated LRTD |
|-----------------|--|

End point description:

Severe RSV-associated LRTD is defined by the presence of clinical evidence of at least 1 sign or symptom of ARD and at least 1 of the following signs or symptoms with onset ≥ 14 days following vaccination until the end of one RSV season (up to 12 months after vaccination), confirmed and documented by a medical professional, together with RSV disease confirmed by polymerase chain reaction (PCR): 1) hypoxemia (oxygen saturation $< 92\%$ at rest in conjunction with an at least 3% decrease from baseline); 2) respiratory rate > 25 breaths/Min; 3) imaging evidence of new onset of bronchitis, bronchiolitis, or pneumonia.

Population: Full Analysis Set.

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

End point timeframe:

From 14 days post-vaccination up to the end of one RSV season

| End point values | MVA-BN-RSV | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 9160 | 9188 | | |
| Units: Subjects | 0 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-specific Serum IgG Antibody Titers

| | |
|-----------------|--|
| End point title | RSV-specific Serum IgG Antibody Titers |
|-----------------|--|

End point description:

Geometric Mean Titers (GMTs) based on RSV-specific Immunoglobulin G (IgG) Enzyme-linked Immunosorbent Assay (ELISA).

Population: Immunogenicity Analysis Set

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

End point timeframe:

2 weeks after vaccination

| End point values | MVA-BN-RSV | Placebo | | |
|--|---------------------------|---------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 309 | 317 | | |
| Units: titre | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Baseline | 1510.6 (1386.4 to 1646.0) | 1590.1 (1468.3 to 1722.0) | | |
| Week 2 | 4335.5 (3963.7 to 4742.2) | 1562.9 (1440.5 to 1695.6) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-specific Serum Neutralizing Antibody Titers (Subtype A)

| | |
|-----------------|---|
| End point title | RSV-specific Serum Neutralizing Antibody Titers (Subtype A) |
|-----------------|---|

End point description:

Geometric Mean Titers (GMTs) based on RSV-specific Plaque Reduction Neutralization Test (PRNT; against subtype A). Results below the lower limit of quantitation (LLOQ) are included with a value of 1/2 LLOQ.

Population: Immunogenicity Analysis Set

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

End point timeframe:

2 weeks after vaccination

| End point values | MVA-BN-RSV | Placebo | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 309 | 317 | | |
| Units: titre | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Baseline | 275.1 (249.4 to 303.4) | 310.6 (280.5 to 343.9) | | |
| Week 2 | 482.3 (436.9 to 532.5) | 307.7 (276.5 to 342.4) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-specific Serum Neutralizing Antibody Titers (Subtype B)

| | |
|--|---|
| End point title | RSV-specific Serum Neutralizing Antibody Titers (Subtype B) |
| End point description: | |
| Geometric Mean Titers (GMTs) based on RSV-specific Plaque Reduction Neutralization Test (PRNT; against subtype B). Results below the lower limit of quantitation (LLOQ) are included with a value of 1/2 LLOQ. | |
| Population: Immunogenicity Analysis Set | |
| End point type | Secondary |
| End point timeframe: | |
| 2 weeks after vaccination | |

| End point values | MVA-BN-RSV | Placebo | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 309 | 317 | | |
| Units: titre | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Baseline | 289.5 (251.5 to 333.1) | 336.5 (292.1 to 387.5) | | |
| Week 2 | 475.3 (419.7 to 538.3) | 307.6 (265.4 to 356.5) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 24 months (planned)

Adverse event reporting additional description:

Serious adverse events were to be reported during the entire study, non-serious adverse events within 4 weeks after vaccination.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 25.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------|
| Reporting group title | MVA-BN-RSV |
|-----------------------|------------|

Reporting group description:

Single administration of MVA-BN-RSV vaccine with a titer of at least 3 x 10E8 infectious units (Inf.U)/0.5mL (intramuscular injection)

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

Reporting group description:

Single administration of Tris-buffered Saline (TBS) (intramuscular injection; 0.5mL)

| Serious adverse events | MVA-BN-RSV | Placebo | |
|---|--------------------|--------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 517 / 9389 (5.51%) | 422 / 8959 (4.71%) | |
| number of deaths (all causes) | 41 | 34 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Neoplasm malignant | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Bladder cancer | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain neoplasm | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Gastrointestinal stromal tumour subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Throat cancer subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of colon subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign renal neoplasm subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder cancer stage 0, with cancer in situ subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer metastatic subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic lymphocytic leukaemia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial cancer | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal adenocarcinoma | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (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 recurrent | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Malignant peritoneal neoplasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mantle cell lymphoma | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastases to abdominal wall | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Prostate cancer stage I | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsil cancer | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transitional cell carcinoma | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma pancreas | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Bladder neoplasm | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone cancer | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Brain cancer metastatic | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac myxoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Central nervous system lymphoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangiocarcinoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic myeloid leukaemia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon cancer | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| 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 | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Intraductal proliferative breast lesion | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Invasive ductal breast carcinoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung carcinoma cell type unspecified stage IV | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Marginal zone lymphoma recurrent | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-small cell lung cancer | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Oesophageal cancer metastatic | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Oncocytoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma cell myeloma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salivary gland neoplasm | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testis cancer | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 4 / 8959 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stenosis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 9389 (0.02%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial occlusive disease | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bleeding varicose vein | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Internal haemorrhage | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant hypertension | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery thrombosis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm rupture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Aortic dissection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Circulatory collapse | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic venous thrombosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral ischaemia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Gallbladder operation | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip surgery | | | |

| | | | |
|--|-------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia repair | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 11 / 9389 (0.12%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 9 / 9389 (0.10%) | 7 / 8959 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 9 | 0 / 7 | |
| Chest discomfort | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gait disturbance | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac death | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cyst | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug withdrawal syndrome | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injection site erythema | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injection site pruritus | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple organ dysfunction syndrome | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden cardiac death | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Calcinosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysplasia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometrial thickening | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Female genital tract fistula | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 13 / 9389 (0.14%) | 18 / 8959 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Dyspnoea | | | |
| subjects affected / exposed | 10 / 9389 (0.11%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 9 / 9389 (0.10%) | 8 / 8959 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 13 / 8959 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Hypoxia | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 9389 (0.03%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute pulmonary oedema | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Asthma | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory failure | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthma-chronic obstructive pulmonary disease overlap syndrome | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis chronic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic respiratory failure | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive sleep apnoea syndrome | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary artery occlusion | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary thrombosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wheezing | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental status changes | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal ideation | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol use disorder | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar disorder | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional state | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression suicidal | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental disorder | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizophrenia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Substance use disorder | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol abuse | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disorientation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device dislocation | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device loosening | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Gastrointestinal stoma output increased | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| SARS-CoV-2 test positive | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood magnesium decreased | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Cardiac murmur | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart rate increased | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 4 / 8959 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Multiple injuries | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fracture | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal fracture | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical vertebral fracture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Contusion | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial bones fracture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula fracture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar vertebral fracture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck injury | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Patella fracture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative ileus | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib fracture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 5 / 8959 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seroma | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic injury | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon injury | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon rupture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thoracic vertebral fracture | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acetabulum fracture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 4 / 8959 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extradural haematoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 4 / 8959 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal injury | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| 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 | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional overdose | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| 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 | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural intestinal perforation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Spinal column injury | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stoma site haemorrhage | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 21 / 9389 (0.22%) | 14 / 8959 (0.16%) | |
| occurrences causally related to treatment / all | 1 / 21 | 1 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute myocardial infarction | | | |
| subjects affected / exposed | 15 / 9389 (0.16%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 11 / 9389 (0.12%) | 13 / 8959 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 5 | |
| Angina pectoris | | | |
| subjects affected / exposed | 9 / 9389 (0.10%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 8 / 9389 (0.09%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 6 / 9389 (0.06%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 1 | |
| Cardiac failure | | | |
| subjects affected / exposed | 6 / 9389 (0.06%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 6 / 9389 (0.06%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure acute | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 9389 (0.03%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block complete | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute left ventricular failure | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic valve stenosis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmic storm | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular block | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bundle branch block left | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Congestive cardiomyopathy | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus arrest | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus node dysfunction | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 4 / 8959 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure chronic | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiomyopathy | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiovascular disorder | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulseless electrical activity | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 15 / 9389 (0.16%) | 11 / 8959 (0.12%) | |
| occurrences causally related to treatment / all | 2 / 15 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 12 / 9389 (0.13%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 9 / 9389 (0.10%) | 8 / 8959 (0.09%) | |
| occurrences causally related to treatment / all | 2 / 9 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metabolic encephalopathy | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myelopathy | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcoholic seizure | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Altered state of consciousness | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amnesia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ataxia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal ganglia stroke | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery occlusion | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrospinal fluid leakage | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolic stroke | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paresis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Monoplegia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paralysis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Speech disorder | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bell's palsy | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical spinal cord paralysis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysarthria | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial paralysis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| 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 | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic stroke | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lacunar stroke | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar radiculopathy | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mononeuropathy | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Normal pressure hydrocephalus | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Partial seizures | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal claudication | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic encephalopathy | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 4 / 8959 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood loss anaemia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune thrombocytopenia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |

| | | | |
|---|------------------|------------------|--|
| Vertigo | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo positional | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Diplopia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lens dislocation | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Macular oedema | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glaucoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|------------------|------------------|--|
| Abdominal pain | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ischaemic | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal ulcer haemorrhage | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal hernia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal incarcerated hernia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diaphragmatic hernia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum intestinal haemorrhagic | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal obstruction | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| 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 | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer haemorrhage | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctitis ulcerative | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterovesical fistula | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric ulcer | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| 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 | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obstructive pancreatitis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Volvulus of small bowel | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cirrhosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatotoxicity | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile duct stenosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic lesion | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis alcoholic | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic foot | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient acantholytic dermatosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| 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 | 7 / 9389 (0.07%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| End stage renal disease | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mixed incontinence | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary retention | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder spasm | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric obstruction | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary bladder polyp | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Goitre | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|-------------------|-------------------|--|
| Osteoarthritis | | | |
| subjects affected / exposed | 14 / 9389 (0.15%) | 24 / 8959 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar spinal stenosis | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| 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 | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint swelling | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal retrolisthesis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal stenosis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spondylolisthesis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot deformity | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fracture pain | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc compression | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondrosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scoliosis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft tissue swelling | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemarthrosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint range of motion decreased | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal osteoarthritis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral osteophyte | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Pneumonia | | | |
| subjects affected / exposed | 37 / 9389 (0.39%) | 23 / 8959 (0.26%) | |
| occurrences causally related to treatment / all | 1 / 38 | 1 / 24 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 12 / 9389 (0.13%) | 9 / 8959 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 10 / 9389 (0.11%) | 6 / 8959 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COVID-19 | | | |
| subjects affected / exposed | 9 / 9389 (0.10%) | 5 / 8959 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 9 / 9389 (0.10%) | 7 / 8959 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 6 / 9389 (0.06%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis infective | | | |
| subjects affected / exposed | 5 / 9389 (0.05%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Influenza | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 4 / 8959 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Abscess limb | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metapneumovirus pneumonia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall abscess | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess intestinal | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis bacterial | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Campylobacter infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis staphylococcal | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complicated appendicitis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (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 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fournier's gangrene | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis A | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective exacerbation of chronic obstructive airways disease | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestine infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Norovirus infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia influenzal | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis infective | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| External ear cellulitis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fungaemia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site abscess | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected bite | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| 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 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal candidiasis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic abscess | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural infection | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scrotal cellulitis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin bacterial infection | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal sepsis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vestibular neuronitis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval abscess | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 6 / 9389 (0.06%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 4 / 9389 (0.04%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 3 / 9389 (0.03%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 3 / 8959 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemic hyperosmolar nonketotic syndrome | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 2 / 8959 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypervolaemia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 2 / 9389 (0.02%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failure to thrive | | | |
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypomagnesaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 9389 (0.01%) | 0 / 8959 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cachexia | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gout | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 0 / 9389 (0.00%) | 1 / 8959 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0.5 %

| Non-serious adverse events | MVA-BN-RSV | Placebo | |
|---|-------------------|-------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 82 / 9389 (0.87%) | 82 / 8959 (0.92%) | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 82 / 9389 (0.87%) | 82 / 8959 (0.92%) | |
| occurrences (all) | 83 | 84 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported