



Clinical trial results:

A 12-Week Multicenter, Randomized, Double-Blind, Placebo Controlled Study Comparing the Efficacy and Safety of LY2439821 to Etanercept and Placebo in Patients with Moderate to Severe Plaque Psoriasis with a Long-Term Extension Period

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2011-004368-31 |
| Trial protocol | HU DE BG PL |
| Global end of trial date | 22 July 2019 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 02 August 2020 |
| First version publication date | 02 August 2020 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | I1F-MC-RHBC |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|---------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01646177 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Trial Number: 13685 |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Eli Lilly and Company |
| Sponsor organisation address | Lilly Corporate Center, Indianapolis, IN, United States, 46285 |
| Public contact | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly, |
| Scientific contact | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559, |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|--------------|
| Analysis stage | Final |
| Date of interim/final analysis | 22 July 2019 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 July 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

This study will assess the safety and efficacy of ixekizumab (LY2439821), compared to etanercept and placebo in participants with moderate to severe chronic plaque psoriasis.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 28 July 2012 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Argentina: 21 |
| Country: Number of subjects enrolled | Chile: 76 |
| Country: Number of subjects enrolled | Mexico: 5 |
| Country: Number of subjects enrolled | Bulgaria: 48 |
| Country: Number of subjects enrolled | Germany: 312 |
| Country: Number of subjects enrolled | Hungary: 113 |
| Country: Number of subjects enrolled | Poland: 39 |
| Country: Number of subjects enrolled | Russian Federation: 77 |
| Country: Number of subjects enrolled | Canada: 152 |
| Country: Number of subjects enrolled | United States: 503 |
| Worldwide total number of subjects | 1346 |
| EEA total number of subjects | 512 |

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) | 1238 |
| From 65 to 84 years | 107 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

This study has 4 periods: Period 1 - Screening; Period 2 - Blinded Induction Dosing Period (Weeks 0 to 12); Period 3 - Long-Term Extension Period (Weeks 12 to 264); Period 4 - Post-Treatment Follow-Up Period (Minimum of 12 Weeks)

Period 1

| | |
|------------------------------|--|
| Period 1 title | Blinded Induction Dosing (Week 0-12) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

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

Arm description:

Placebo (PBO) for ixekizumab (Week 0) given as 2 subcutaneous (SC) injections followed by placebo for ixekizumab Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 up to Week 12.

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Administered SC

| | |
|------------------|------------------------|
| Arm title | 50 mg Etanercept (ETN) |
|------------------|------------------------|

Arm description:

Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12.

Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10).

| | |
|--|------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Etanercept |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12

| | |
|--|------------------------|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10).

| | |
|------------------|---|
| Arm title | 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
|------------------|---|

Arm description:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8). Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10. Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.

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

Dosage and administration details:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8).

| | |
|--|--------------------------|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12. Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10.

| | |
|------------------|---|
| Arm title | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|------------------|---|

Arm description:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).

Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.

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

Dosage and administration details:

A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10).

| | |
|--|--------------------------|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12.

| Number of subjects in period 1 | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
|--|---------|------------------------|---|
| | | | |
| Started | 193 | 382 | 386 |
| Received at least one dose of study drug | 193 | 382 | 382 |
| Completed | 183 | 369 | 360 |
| Not completed | 10 | 13 | 26 |
| Consent withdrawn by subject | 3 | 2 | 4 |
| Physician decision | 1 | 2 | 1 |
| Adverse event, non-fatal | 2 | 4 | 9 |
| Lost to follow-up | 3 | 2 | 2 |
| Protocol deviation | 1 | 3 | 8 |
| Lack of efficacy | - | - | 2 |

| Number of subjects in period 1 | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|--|---|
| Started | 385 |
| Received at least one dose of study drug | 384 |
| Completed | 363 |
| Not completed | 22 |
| Consent withdrawn by subject | 4 |
| Physician decision | 2 |
| Adverse event, non-fatal | 8 |
| Lost to follow-up | - |
| Protocol deviation | 7 |
| Lack of efficacy | 1 |

Period 2

| | |
|------------------------------|--|
| Period 2 title | Long-Term Extension Period (Week 12-264) |
| Is this the baseline period? | No |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|---|--------------|
| Are arms mutually exclusive? | No |
| Arm title | PBO/IXE80Q4W |
| Arm description: | |
| Participants who received placebo during the induction period and received 80 mg ixekizumab SC injection every four weeks (IXE80Q4W) in the Long-term extension period. | |
| Arm type | Experimental |

| | |
|--|------------------------|
| Investigational medicinal product name | Ixekizumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants received a starting dose of 160 mg of ixekizumab as 2 SC injections at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

| | |
|------------------|--------------|
| Arm title | ETN/IXE80Q4W |
|------------------|--------------|

Arm description:

Participants who received Etanercept during the induction period and received IXE80Q4W in the long-term extension period.

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

Dosage and administration details:

Participants received placebo as 2 SC injections at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

| | |
|------------------|-------------------|
| Arm title | IXE80Q4W/IXE80Q4W |
|------------------|-------------------|

Arm description:

Participants who received 80 mg ixekizumab Q4W during the induction period and received IXE80Q4W in the long-term extension period.

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

Dosage and administration details:

Participants received 80 mg ixekizumab as 1 SC injection + a placebo injection at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

| | |
|------------------|-------------------|
| Arm title | IXE80Q2W/IXE80Q4W |
|------------------|-------------------|

Arm description:

Participants who received 80 mg ixekizumab Q2W (IXE80Q2W) during the induction period and received IXE80Q4W in the long-term extension period.

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

Dosage and administration details:

Participants received 80 mg ixekizumab as 1 SC injection + a placebo injection at Week 12 and 80 mg ixekizumab as 1 SC injection Q4W thereafter.

| Number of subjects in period 2 | PBO/IXE80Q4W | ETN/IXE80Q4W | IXE80Q4W/IXE80Q4W |
|--|--------------|--------------|-------------------|
| Started | 183 | 369 | 360 |
| Received at least one dose of study drug | 183 | 369 | 360 |
| Completed | 135 | 256 | 244 |
| Not completed | 48 | 113 | 116 |
| Adverse event, serious fatal | 1 | 3 | 1 |
| Parent/Caregiver Decision | - | - | - |
| Consent withdrawn by subject | 11 | 30 | 29 |
| Physician decision | 3 | 5 | 5 |
| Clinical Relapse | 1 | 1 | 1 |
| Adverse event, non-fatal | 16 | 34 | 43 |
| Sponsor Decision | 3 | 2 | 2 |
| Lost to follow-up | 6 | 17 | 23 |
| Missing Disposition Form | - | 3 | 2 |
| Lack of efficacy | 6 | 14 | 10 |
| Protocol deviation | 1 | 4 | - |

| Number of subjects in period 2 | IXE80Q2W/IXE80Q4W |
|--|-------------------|
| Started | 362 |
| Received at least one dose of study drug | 362 |
| Completed | 255 |
| Not completed | 107 |
| Adverse event, serious fatal | 3 |
| Parent/Caregiver Decision | 1 |
| Consent withdrawn by subject | 27 |
| Physician decision | 5 |
| Clinical Relapse | 4 |
| Adverse event, non-fatal | 30 |
| Sponsor Decision | 2 |
| Lost to follow-up | 18 |
| Missing Disposition Form | 1 |
| Lack of efficacy | 11 |
| Protocol deviation | 5 |

Period 3

| | |
|------------------------------|--|
| Period 3 title | Follow-Up Period (Minimum of 12 Weeks) |
| Is this the baseline period? | No |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|----------------------|
| Are arms mutually exclusive? | No |
| Arm title | PBO Follow-Up Period |

Arm description:

Participants who received PBO in the Induction Period and entered the Post-Treatment Follow-up Period.

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants who received PBO in the Induction Period and entered the Post-Treatment Follow-up Period.

| | |
|------------------|----------------------|
| Arm title | ETN Follow-Up Period |
|------------------|----------------------|

Arm description:

Participants who received etanercept (ETN) in the Induction Period and entered the Post-Treatment Follow-up Period.

| | |
|--|------------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Etanercept |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants who received etanercept (ETN) in the Induction Period and entered the Post-Treatment Follow-up Period.

| | |
|------------------|---------------------------|
| Arm title | IXE80Q4W Follow-Up Period |
|------------------|---------------------------|

Arm description:

Participants who received 80 mg ixm Q4W in the Induction Period and entered the Post-Treatment Follow-up Period.

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

Dosage and administration details:

Participants who received 80 mg ixm Q4W in the Induction Period and entered the Post-Treatment Follow-up Period.

| | |
|------------------|---------------------------|
| Arm title | IXE80Q2W Follow-Up Period |
|------------------|---------------------------|

Arm description:

Participants who received 80 mg ixm Q2W in the Induction Period and entered the Post-Treatment Follow-up Period.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|------------------------|
| Investigational medicinal product name | Ixekizumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants who received 80 mg ixekizumab Q2W in the Induction Period and entered the Post-Treatment Follow-up Period.

| Number of subjects in period 3 | PBO Follow-Up Period | ETN Follow-Up Period | IXE80Q4W Follow-Up Period |
|--|----------------------|----------------------|---------------------------|
| Started | 157 | 309 | 305 |
| Received at least one dose of study drug | 157 | 309 | 305 |
| Completed | 126 | 233 | 225 |
| Not completed | 31 | 76 | 80 |
| Adverse event, serious fatal | 1 | - | 1 |
| Consent withdrawn by subject | 7 | 21 | 19 |
| Physician decision | 1 | 2 | 2 |
| Clinical Relapse | - | 1 | 1 |
| Adverse event, non-fatal | 13 | 28 | 34 |
| Sponsor Decision | - | 1 | 1 |
| Lost to follow-up | 4 | 8 | 9 |
| Entry Criteria Not Met | - | - | 1 |
| Lack of efficacy | 4 | 9 | 8 |
| Protocol deviation | 1 | 6 | 4 |

| Number of subjects in period 3 | IXE80Q2W Follow-Up Period |
|--|---------------------------|
| Started | 313 |
| Received at least one dose of study drug | 313 |
| Completed | 230 |
| Not completed | 83 |
| Adverse event, serious fatal | 1 |
| Consent withdrawn by subject | 19 |
| Physician decision | 3 |
| Clinical Relapse | 3 |
| Adverse event, non-fatal | 30 |
| Sponsor Decision | 1 |
| Lost to follow-up | 9 |
| Entry Criteria Not Met | 1 |
| Lack of efficacy | 9 |
| Protocol deviation | 7 |

Baseline characteristics

Reporting groups

| | |
|---|---|
| Reporting group title | Placebo |
| Reporting group description: Placebo (PBO) for ixekizumab (Week 0) given as 2 subcutaneous (SC) injections followed by placebo for ixekizumab Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 up to Week 12. | |
| Reporting group title | 50 mg Etanercept (ETN) |
| Reporting group description: Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12. Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10). | |
| Reporting group title | 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Reporting group description: A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8). Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10. Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12. | |
| Reporting group title | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Reporting group description: A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12. | |

| Reporting group values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
|---|---------|------------------------|---|
| Number of subjects | 193 | 382 | 386 |
| Age categorical | | | |
| Units: Subjects | | | |
| <=18 years | 0 | 0 | 0 |
| Between 18 and 65 years | 180 | 349 | 358 |
| >=65 years | 13 | 33 | 28 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 56 | 113 | 128 |
| Male | 137 | 269 | 258 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 25 | 52 | 50 |
| Not Hispanic or Latino | 133 | 263 | 269 |
| Unknown or Not Reported | 35 | 67 | 67 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 1 | 4 | 4 |
| Asian | 7 | 11 | 11 |
| Native Hawaiian or Other Pacific Islander | 0 | 1 | 1 |
| Black or African American | 8 | 10 | 9 |
| White | 176 | 351 | 360 |
| More than one race | 1 | 5 | 1 |
| Unknown or Not Reported | 0 | 0 | 0 |

| | | | |
|---|----|-----|-----|
| Region of Enrollment Units: Subjects | | | |
| Argentina | 2 | 7 | 6 |
| Chile | 11 | 21 | 22 |
| Mexico | 1 | 2 | 1 |
| Bulgaria | 9 | 12 | 14 |
| Germany | 45 | 87 | 90 |
| Hungary | 18 | 31 | 31 |
| Poland | 5 | 10 | 11 |
| Russia | 11 | 22 | 20 |
| Canada | 22 | 44 | 44 |
| United States | 69 | 146 | 147 |

| | | | |
|--|---|-------|--|
| Reporting group values | 80 mg ixekizumab Dosing Regimen 1 (Q2W) | Total | |
| Number of subjects | 385 | 1346 | |
| Age categorical Units: Subjects | | | |
| <=18 years | 0 | 0 | |
| Between 18 and 65 years | 351 | 1238 | |
| >=65 years | 34 | 108 | |
| Gender categorical Units: Subjects | | | |
| Female | 131 | 428 | |
| Male | 254 | 918 | |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 57 | 184 | |
| Not Hispanic or Latino | 259 | 924 | |
| Unknown or Not Reported | 69 | 238 | |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 1 | 10 | |
| Asian | 12 | 41 | |
| Native Hawaiian or Other Pacific Islander | 4 | 6 | |
| Black or African American | 5 | 32 | |
| White | 361 | 1248 | |
| More than one race | 2 | 9 | |
| Unknown or Not Reported | 0 | 0 | |
| Region of Enrollment Units: Subjects | | | |
| Argentina | 6 | 21 | |
| Chile | 22 | 76 | |
| Mexico | 1 | 5 | |
| Bulgaria | 13 | 48 | |
| Germany | 90 | 312 | |
| Hungary | 33 | 113 | |
| Poland | 13 | 39 | |
| Russia | 24 | 77 | |
| Canada | 42 | 152 | |
| United States | 141 | 503 | |

End points

End points reporting groups

| | |
|---|---|
| Reporting group title | Placebo |
| Reporting group description: Placebo (PBO) for ixekizumab (Week 0) given as 2 subcutaneous (SC) injections followed by placebo for ixekizumab Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 up to Week 12. | |
| Reporting group title | 50 mg Etanercept (ETN) |
| Reporting group description: Etanercept 50 mg (1 SC injection) given twice weekly (every 3-4 days) starting at Week 0 and up to Week 12. Placebo for ixekizumab given as 2 SC injections (Week 0) followed by placebo for ixekizumab Q2W given as 1 SC injection (Weeks 2, 4, 6, 8, and 10). | |
| Reporting group title | 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Reporting group description: A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q4W (Weeks 4 and 8). Placebo for ixekizumab given as 1 SC injection at Weeks 2, 6, and 10. Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12. | |
| Reporting group title | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Reporting group description: A starting dose of 160 mg (Week 0) given as 2 SC injections followed by 80 mg given as 1 SC injection Q2W (Weeks 2, 4, 6, 8, and 10). Placebo for etanercept (1 SC injection) given twice weekly starting at Week 0 up to Week 12. | |
| Reporting group title | PBO/IXE80Q4W |
| Reporting group description: Participants who received placebo during the induction period and received 80 mg ixekizumab SC injection every four weeks (IXE80Q4W) in the Long-term extension period. | |
| Reporting group title | ETN/IXE80Q4W |
| Reporting group description: Participants who received Etanercept during the induction period and received IXE80Q4W in the long-term extension period. | |
| Reporting group title | IXE80Q4W/IXE80Q4W |
| Reporting group description: Participants who received 80 mg ixekizumab Q4W during the induction period and received IXE80Q4W in the long-term extension period. | |
| Reporting group title | IXE80Q2W/IXE80Q4W |
| Reporting group description: Participants who received 80 mg ixekizumab Q2W (IXE80Q2W) during the induction period and received IXE80Q4W in the long-term extension period. | |
| Reporting group title | PBO Follow-Up Period |
| Reporting group description: Participants who received PBO in the Induction Period and entered the Post-Treatment Follow-up Period. | |
| Reporting group title | ETN Follow-Up Period |
| Reporting group description: Participants who received etanercept (ETN) in the Induction Period and entered the Post-Treatment Follow-up Period. | |
| Reporting group title | IXE80Q4W Follow-Up Period |
| Reporting group description: Participants who received 80 mg ixekizumab Q4W in the Induction Period and entered the Post-Treatment Follow-up Period. | |
| Reporting group title | IXE80Q2W Follow-Up Period |
| Reporting group description: Participants who received 80 mg ixekizumab Q2W in the Induction Period and entered the Post-Treatment Follow-up Period. | |

Primary: Number of participants achieving a static Physician Global Assessment (sPGA) of (0, 1) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA)

| | |
|-----------------|---|
| End point title | Number of participants achieving a static Physician Global Assessment (sPGA) of (0, 1) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA) |
|-----------------|---|

End point description:

The sPGA is a physician's determination of the participant's psoriasis lesions overall at a given time point categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant's psoriasis is assessed as clear (0), minimal (1), mild (2), moderate (3), severe (4), or very severe (5). An sPGA (0,1) response was defined as a post-baseline sPGA score of 0 or 1. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

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

End point timeframe:

Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|--------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 193 ^[1] | 382 ^[2] | 386 ^[3] | 385 ^[4] |
| Units: participants | 13 | 159 | 291 | 310 |

Notes:

[1] - All randomized participants.

[2] - All randomized participants.

[3] - All randomized participants.

[4] - All randomized participants.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | sPGA Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 575 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|----------------------------|---|
| Statistical analysis title | sPGA Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 579 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | sPGA Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 578 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Primary: Number of Participants Achieving Psoriasis Area and Severity Index $\geq 75\%$ (PASI 75) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

| | |
|-----------------|---|
| End point title | Number of Participants Achieving Psoriasis Area and Severity Index $\geq 75\%$ (PASI 75) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI) |
|-----------------|---|

End point description:

The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation (scaling), erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no psoriasis to 72 for the most severe disease. Participants achieving PASI 75 was defined as having an improvement of at least 75% in the PASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

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

End point timeframe:

Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|--------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 193 ^[5] | 382 ^[6] | 386 ^[7] | 385 ^[8] |
| Units: participants | 14 | 204 | 325 | 336 |

Notes:

[5] - All randomized participants.

[6] - All randomized participants.

[7] - All randomized participants.

[8] - All randomized participants.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | PASI 75 Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 575 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | PASI 75 Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 579 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | PASI 75 Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 578 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of participants achieving an sPGA (0) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA)

| | |
|-----------------|---|
| End point title | Number of participants achieving an sPGA (0) (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: sPGA) |
|-----------------|---|

End point description:

The sPGA is a physician's determination of the participant's psoriasis lesions overall at a given time point categorized by descriptions for induration, erythema, and scaling. For the analysis of responses, the participant's psoriasis is assessed as clear (0), minimal (1), mild (2), moderate (3), severe (4), or very severe (5). An sPGA (0) response was defined as a post-baseline sPGA score of 0. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

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

End point timeframe:

Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|--------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 193 ^[9] | 382 ^[10] | 386 ^[11] | 385 ^[12] |
| Units: participants | 0 | 33 | 139 | 155 |

Notes:

[9] - All randomized participants.

[10] - All randomized participants.

[11] - All randomized participants.

[12] - All randomized participants.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | sPGA (0) Statistical Analysis 1 |
| Comparison groups | 50 mg Etanercept (ETN) v Placebo |
| Number of subjects included in analysis | 575 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | sPGA (0) Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 579 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | sPGA (0) Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 578 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Participants Achieving ≥90% (PASI 90) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

| | |
|-----------------|--|
| End point title | Number of Participants Achieving ≥90% (PASI 90) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI) |
|-----------------|--|

End point description:

The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation (scaling), erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no psoriasis to 72 for the most severe disease. Participants achieving PASI 90 were defined as having an improvement of at least 90% in the PASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 193 ^[13] | 382 ^[14] | 386 ^[15] | 385 ^[16] |
| Units: participants | 6 | 98 | 252 | 262 |

Notes:

[13] - All randomized participants.

[14] - All randomized participants.

[15] - All randomized participants.

[16] - All randomized participants.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | PASI 90 Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 575 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | PASI 90 Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 579 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|-----------------------------------|---|
| Statistical analysis title | PASI 90 Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 578 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Participants Achieving 100% (PASI 100) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI)

| | |
|-----------------|---|
| End point title | Number of Participants Achieving 100% (PASI 100) Improvement (Efficacy of ixekizumab in participants with moderate to severe chronic plaque psoriasis. Measure: PASI) |
|-----------------|---|

End point description:

The PASI combines assessments of the extent of body-surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of desquamation (scaling), erythema, and plaque induration/infiltration (thickness) in each region, yielding an overall score of 0 for no psoriasis to 72 for the most severe disease. Participants achieving PASI 100 were defined as having an improvement of at least 100% in the PASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the Non-Responder Imputation (NRI) analysis.

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

End point timeframe:

Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 193 ^[17] | 382 ^[18] | 386 ^[19] | 385 ^[20] |
| Units: participants | 0 | 28 | 135 | 145 |

Notes:

[17] - All randomized participants.

[18] - All randomized participants.

[19] - All randomized participants.

[20] - All randomized participants.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | PASI 100 Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 575 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | PASI 100 Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 579 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | PASI 100 Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 578 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Participants Achieving an Itch Numeric Rating Scale (NRS) ≥ 4 Point Reduction [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)]

| | |
|-----------------|---|
| End point title | Number of Participants Achieving an Itch Numeric Rating Scale (NRS) ≥ 4 Point Reduction [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)] |
|-----------------|---|

End point description:

The Itch NRS is a participant-administered single-item 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Participants indicate their overall severity of itching from Psoriasis by circling the number that best describes the worst level of itching in the past 24 hours. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

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

End point timeframe:

Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 158 ^[21] | 312 ^[22] | 313 ^[23] | 320 ^[24] |
| Units: participants | 33 | 200 | 250 | 264 |

Notes:

[21] - All randomized participants and had an Itch NRS score ≥ 4 at baseline.

[22] - All randomized participants and had an Itch NRS score ≥ 4 at baseline.

[23] - All randomized participants and had an Itch NRS score ≥ 4 at baseline.

[24] - All randomized participants and had an Itch NRS score ≥ 4 at baseline.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | Itch NRS Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 470 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Itch NRS Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 471 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Itch NRS Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 478 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score

| | |
|-----------------|---|
| End point title | Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score |
|-----------------|---|

End point description:

The DLQI is a simple, participant-administered, 10 question, validated, quality-of-life questionnaire that covers 6 domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "not at all," "a lot," and "very much," with corresponding scores of 1, 2, and 3, respectively, and unanswered ("not relevant") responses scored as "0." Totals range from 0 to 30 (less to more impairment), and a 5 point change from baseline is considered clinically relevant. Least Square (LS) Means in total DLQI score were calculated using Mixed Model Repeated Measures (MMRM) with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 191 ^[25] | 376 ^[26] | 375 ^[27] | 377 ^[28] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | -1.7 (± 0.32) | -8.0 (± 0.23) | -9.6 (± 0.23) | -10.2 (± 0.23) |

Notes:

[25] - All randomized participants who had at least one post-dose measurement of DLQI.

[26] - All randomized participants who had at least one post-dose measurement of DLQI.

[27] - All randomized participants who had at least one post-dose measurement of DLQI.

[28] - All randomized participants who had at least one post-dose measurement of DLQI.

Statistical analyses

| Statistical analysis title | DLQI Statistical Analysis 1 |
|---|----------------------------------|
| Comparison groups | 50 mg Etanercept (ETN) v Placebo |
| Number of subjects included in analysis | 567 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| Statistical analysis title | DLQI Statistical Analysis 2 |
|---|---|
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 566 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| Statistical analysis title | DLQI Statistical Analysis 3 |
|---|---|
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 568 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

Secondary: Change from Baseline in Nail Psoriasis Severity Index (NAPSI) Score

| | |
|-----------------|---|
| End point title | Change from Baseline in Nail Psoriasis Severity Index (NAPSI) Score |
|-----------------|---|

End point description:

The NAPSI is a numeric, reproducible, objective tool used to evaluate the severity of fingernail bed psoriasis and fingernail matrix psoriasis by area of involvement in the fingernail unit. The fingernail is divided with imaginary horizontal and longitudinal lines into quadrants. Each fingernail is given a score for fingernail bed psoriasis: 0 (none) to 4 (psoriasis in 4 quadrants of the nail) and fingernail matrix psoriasis (0 to 4) depending on the presence (score of 1) or absence (score of 0) of any of the features of fingernail bed and fingernail matrix psoriasis in each quadrant. The NAPSI score of a fingernail is the sum of scores in fingernail bed and fingernail matrix from each quadrant (maximum of 8). Each fingernail is evaluated, and the sum of all the fingernails is the total NAPSI score (range, 0 to 80). LS Means in NAPSI score were calculated using MMRM with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 115 ^[29] | 233 ^[30] | 226 ^[31] | 228 ^[32] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | 1.6362 (± 1.0991) | -6.4015 (± 0.7716) | -9.9793 (± 0.7838) | -10.4145 (± 0.7820) |

Notes:

[29] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

[30] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

[31] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

[32] - All randomized participants with fingernail involvement at baseline and had ≥1 post baseline.

Statistical analyses

| Statistical analysis title | NAPSI Statistical Analysis 1 |
|---|----------------------------------|
| Comparison groups | 50 mg Etanercept (ETN) v Placebo |
| Number of subjects included in analysis | 348 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| Statistical analysis title | NAPSI Statistical Analysis 2 |
|---|---|
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 341 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| | |
|---|---|
| Statistical analysis title | NAPSI Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 343 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

Secondary: Percent of Body Surface Area (BSA) Involvement of Psoriasis

| | |
|---|---|
| End point title | Percent of Body Surface Area (BSA) Involvement of Psoriasis |
| End point description: Percentage involvement of psoriasis on each participants body surface area was assessed by the investigator on a continuous scale from 0% (no involvement) to 100% (full involvement), in which 1% corresponds to the size of the participant's hand (including palm, fingers and thumb). LS Means in BSA were calculated using MMRM with baseline BSA as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects. | |
| End point type | Secondary |
| End point timeframe: Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 192 ^[33] | 378 ^[34] | 377 ^[35] | 380 ^[36] |
| Units: Percent | | | | |
| least squares mean (standard error) | -0.7 (± 1.03) | -16.4 (± 0.73) | -23.2 (± 0.73) | -23.2 (± 0.73) |

Notes:

[33] - All randomized participants and had at least one post-dose measurement of BSA.

[34] - All randomized participants and had at least one post-dose measurement of BSA.

[35] - All randomized participants and had at least one post-dose measurement of BSA.

[36] - All randomized participants and had at least one post-dose measurement of BSA.

Statistical analyses

| | |
|-----------------------------------|----------------------------------|
| Statistical analysis title | BSA Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |

| | |
|---|-----------------------|
| Number of subjects included in analysis | 570 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| | |
|---|---|
| Statistical analysis title | BSA Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 569 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| | |
|---|---|
| Statistical analysis title | BSA Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

Secondary: Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Score

| | |
|-----------------|---|
| End point title | Change from Baseline in Psoriasis Scalp Severity Index (PSSI) Score |
|-----------------|---|

End point description:

PSSI is a composite score ranging from 0 (best) to 72 (worst), derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of scalp area involved. LS Means in PSSI score were calculated using MMRM with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

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

End point timeframe:

Baseline, Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 175 ^[37] | 345 ^[38] | 344 ^[39] | 344 ^[40] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | -5.0 (± 0.53) | -15.9 (± 0.38) | -18.2 (± 0.38) | -18.8 (± 0.38) |

Notes:

[37] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.

[38] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.

[39] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.

[40] - All randomized participants and had scalp psoriasis at baseline and had at least one post-dose.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | PSSI Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 520 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| | |
|---|---|
| Statistical analysis title | PSSI Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 519 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| | |
|---|---|
| Statistical analysis title | PSSI Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 519 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

Secondary: Change from Baseline in Quick Inventory of Depressive Symptomatology-Self Report 16 Items (QIDS-SR16) Total Score [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)]

| | |
|-----------------|--|
| End point title | Change from Baseline in Quick Inventory of Depressive Symptomatology-Self Report 16 Items (QIDS-SR16) Total Score [Quality of Life and Outcome Assessments. Measures: Patient Reported Outcomes (PRO)] |
|-----------------|--|

End point description:

The QIDS-SR16 is a self-administered, 16-item instrument in which a participant is asked to consider each statement as it relates to the way they have felt for the past 7 days. There is a 4-point scale for each item ranging from 0 (best) to 3 (worst). The 16 items are scored to give 9 individual depression domains (sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance [initial, middle and late insomnia or hypersomnia], decrease/increase in appetite/weight, and psychomotor agitation/retardation), which are summed to give a single score ranging from 0 to 27,

with higher scores denoting greater symptom severity. LS Means in total QIDS-SR16 score were calculated using the analysis of covariance (ANCOVA) model with treatment, pooled center and baseline QIDS total score. Missing data was imputed by last observation carried forward (LOCF).

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 184 ^[41] | 379 ^[42] | 373 ^[43] | 373 ^[44] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | -0.3 (± 0.20) | -0.5 (± 0.14) | -0.9 (± 0.14) | -1.3 (± 0.14) |

Notes:

[41] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

[42] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

[43] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

[44] - All randomized participants and had at least one post-dose measurement of QIDS-SR16.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | QIDS-SR16 Statistical Analysis 1 |
| Comparison groups | 50 mg Etanercept (ETN) v Placebo |
| Number of subjects included in analysis | 563 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.473 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | QIDS-SR16 Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 557 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.015 |
| Method | ANCOVA |

| | |
|-----------------------------------|---|
| Statistical analysis title | QIDS-SR16 Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |

| | |
|---|---------------|
| Number of subjects included in analysis | 557 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

Secondary: Change From Baseline in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores

| | |
|-----------------|---|
| End point title | Change From Baseline in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores |
|-----------------|---|

End point description:

The SF-36 is a participant-reported outcome measure evaluating participant's health status. It comprises 36 items covering 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, social functioning, mental health, and general health. Items are answered on Likert scales of varying lengths. The 8 domains are regrouped into the PCS and MCS scores. The summary scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. In this study, the SF-36 acute version was used, which has a 1 week recall period. LS Means in SF-36 score were calculated using the ANCOVA model with treatment, pooled center and baseline SF-36 score. Missing data was imputed by last observation carried forward (LOCF).

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

End point timeframe:

Baseline, Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 179 ^[45] | 365 ^[46] | 362 ^[47] | 357 ^[48] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | | | | |
| PCS | -0.2 (± 0.51) | 3.1 (± 0.36) | 4.1 (± 0.36) | 4.0 (± 0.36) |
| MCS | 1.2 (± 0.58) | 2.7 (± 0.40) | 3.8 (± 0.41) | 4.28 (± 0.41) |

Notes:

[45] - All randomized participants and had at least one post-dose measurement of SF-36.

[46] - All randomized participants and had at least one post-dose measurement of SF-36.

[47] - All randomized participants and had at least one post-dose measurement of SF-36.

[48] - All randomized participants and had at least one post-dose measurement of SF-36.

Statistical analyses

| | |
|----------------------------|----------------------------------|
| Statistical analysis title | SF-36 Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |

| | |
|---|---------------|
| Number of subjects included in analysis | 544 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | SF-36 Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 541 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | SF-36 Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 541 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|----------------------------------|
| Statistical analysis title | SF-36 Statistical Analysis 4 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 544 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.031 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | SF-36 Statistical Analysis 5 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 541 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | SF-36 Statistical Analysis 6 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 536 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.01 |
| Method | ANCOVA |

Secondary: Change From Baseline in Patient's Global Assessment of Disease Severity (PatGA)

| | |
|-----------------|---|
| End point title | Change From Baseline in Patient's Global Assessment of Disease Severity (PatGA) |
|-----------------|---|

End point description:

The Patient's Global Assessment of Disease Severity is a single-item participant-reported outcome measure on which participants are asked to rate the severity of their psoriasis "today" from 0 (Clear) = no psoriasis, to 5 (Severe) = the worst their psoriasis has ever been. LS Means in Patient's Global Assessment of Disease Severity score were calculated using MMRM with baseline score as covariate, treatment, pooled center, visit and treatment-by-visit interaction as fixed effects.

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

End point timeframe:

Baseline, Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 192 ^[49] | 377 ^[50] | 375 ^[51] | 376 ^[52] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | -0.5 (± 0.08) | -2.3 (± 0.06) | -3.1 (± 0.06) | -3.1 (± 0.06) |

Notes:

[49] - All randomized participants and had at least one post-dose measurement of PatGA.

[50] - All randomized participants and had at least one post-dose measurement of PatGA.

[51] - All randomized participants and had at least one post-dose measurement of PatGA.

[52] - All randomized participants and had at least one post-dose measurement of PatGA.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | PatGA Statistical Analysis 1 |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 569 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| | |
|---|---|
| Statistical analysis title | PatGA Statistical Analysis 2 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 567 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

| | |
|---|---|
| Statistical analysis title | PatGA Statistical Analysis 3 |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 568 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Mixed models analysis |

Secondary: Number of Participants Achieving Palmoplantar PASI \geq 50% (PPASI 50) Improvement

| | |
|-----------------|--|
| End point title | Number of Participants Achieving Palmoplantar PASI \geq 50% (PPASI 50) Improvement |
|-----------------|--|

End point description:

Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 to 72. Participants achieving PPASI 50 were defined as having an improvement of at least 50% in the PPASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

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

End point timeframe:

Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|--------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 54 ^[53] | 95 ^[54] | 87 ^[55] | 96 ^[56] |
| Units: Participants | 26 | 77 | 75 | 78 |

Notes:

[53] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[54] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[55] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[56] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical Analysis 1 (PPASI 50) |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 149 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 (PPASI 50) |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 141 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 3 (PPASI 50) |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 150 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Participants Achieving Palmoplantar PASI of $\geq 75\%$ (PPASI 75) Improvement

| | |
|-----------------|--|
| End point title | Number of Participants Achieving Palmoplantar PASI of $\geq 75\%$ (PPASI 75) Improvement |
|-----------------|--|

End point description:

Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 to 72. Participants achieving PPASI 75 were defined as having an improvement of at least 75% in the PPASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

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

End point timeframe:

Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|--------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 54 ^[57] | 95 ^[58] | 87 ^[59] | 96 ^[60] |
| Units: Participants | 19 | 63 | 69 | 72 |

Notes:

[57] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[58] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[59] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[60] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

Statistical analyses

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical Analysis 1 (PPASI 75) |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 149 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 (PPASI 75) |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 141 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 3 (PPASI 75) |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 150 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Participants Achieving Palmoplantar PASI of 100% (PPASI 100) Improvement

| | |
|-----------------|--|
| End point title | Number of Participants Achieving Palmoplantar PASI of 100% (PPASI 100) Improvement |
|-----------------|--|

End point description:

Palmoplantar PASI is a composite score derived from the sum scores for erythema, induration, and

desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 to 72. Participants achieving PPASI 100 were defined as having an improvement of 100% in the PPASI scores compared to baseline. Participants who did not meet clinical response criteria or have missing data at Week 12 will be considered non-responders for the NRI analysis.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|--------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 54 ^[61] | 95 ^[62] | 87 ^[63] | 96 ^[64] |
| Units: Participants | 15 | 57 | 54 | 61 |

Notes:

[61] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[62] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[63] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

[64] - All randomized participants and had a diagnosis of palmoplantar psoriasis at baseline.

Statistical analyses

| | |
|---|------------------------------------|
| Statistical analysis title | Statistical Analysis 1 (PPASI 100) |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 149 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|---|
| Statistical analysis title | Statistical Analysis 2 (PPASI 100) |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 141 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|----------------------------|---|
| Statistical analysis title | Statistical Analysis 3 (PPASI 100) |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 150 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Number of Participants With Treatment-Emergent Anti-Ixekizumab Antibodies

| | |
|---|---|
| End point title | Number of Participants With Treatment-Emergent Anti-Ixekizumab Antibodies |
| End point description: The percentage of participants with treatment-emergent positive anti-ixekizumab antibodies at any time post-baseline were summarized by treatment group. Percentage of participants with treatment-emergent positive anti-ixekizumab antibodies were calculated as: number of participants with an evaluable baseline sample and ≥ 1 evaluable post-baseline sample/number of participants in the analysis population * 100. | |
| End point type | Secondary |
| End point timeframe: Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 191 ^[65] | 378 ^[66] | 378 ^[67] | 378 ^[68] |
| Units: Participants | 2 | 8 | 52 | 23 |

Notes:

[65] - All randomized participants who received at least one dose of study treatment and had evaluable data

[66] - All randomized participants who received at least one dose of study treatment and had evaluable data

[67] - All randomized participants who received at least one dose of study treatment and had evaluable data

[68] - All randomized participants who received at least one dose of study treatment and had evaluable data

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Absenteeism of Work Productivity Activity Impairment Questionnaire-Psoriasis (WPAI-PSO)

| | |
|-----------------|---|
| End point title | Change From Baseline in Absenteeism of Work Productivity Activity Impairment Questionnaire-Psoriasis (WPAI-PSO) |
|-----------------|---|

End point description:

The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in

productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 120 ^[69] | 217 ^[70] | 230 ^[71] | 218 ^[72] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | 0.0 (± 0.82) | -2.8 (± 0.62) | -2.0 (± 0.60) | -2.5 (± 0.61) |

Notes:

[69] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

[70] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

[71] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

[72] - All randomized participants and had a least one post-dose measurement of WPAI-PSO.

Statistical analyses

| | |
|---|----------------------------------|
| Statistical analysis title | WPAI-PSO Statistical Analysis 1 |
| Statistical analysis description: | |
| Absenteeism Score | |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 337 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.006 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | WPAI-PSO Statistical Analysis 2 |
| Statistical analysis description: | |
| Absenteeism Score | |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 350 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.045 |
| Method | ANCOVA |

| | |
|-----------------------------------|---------------------------------|
| Statistical analysis title | WPAI-PSO Statistical Analysis 3 |
|-----------------------------------|---------------------------------|

| | |
|---|---|
| Statistical analysis description: | |
| Absenteeism Score | |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 338 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.012 |
| Method | ANCOVA |

Secondary: Change From Baseline in Activity Impairment Score of WPAI-PSO

| | |
|-----------------|---|
| End point title | Change From Baseline in Activity Impairment Score of WPAI-PSO |
|-----------------|---|

End point description:

The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).

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

End point timeframe:

Baseline, Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 184 ^[73] | 376 ^[74] | 375 ^[75] | 373 ^[76] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | -2.5 (± 1.30) | -21.1 (± 0.91) | -23.3 (± 0.92) | -24.5 (± 0.92) |

Notes:

[73] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[74] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[75] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[76] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

Statistical analyses

| | |
|----------------------------|---------------------------------|
| Statistical analysis title | WPAI-PSO Statistical Analysis 4 |
|----------------------------|---------------------------------|

Statistical analysis description:

Activity Impairment Score

| | |
|-------------------|----------------------------------|
| Comparison groups | 50 mg Etanercept (ETN) v Placebo |
|-------------------|----------------------------------|

| | |
|---|---------------|
| Number of subjects included in analysis | 560 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | WPAI-PSO Statistical Analysis 5 |
| Statistical analysis description: | |
| Activity Impairment Score | |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 559 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | WPAI-PSO Statistical Analysis 6 |
| Statistical analysis description: | |
| Activity Impairment Score | |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 557 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

Secondary: Change From Baseline in Presenteeism of WPAI-PSO

| | |
|--|--|
| End point title | Change From Baseline in Presenteeism of WPAI-PSO |
| End point description: | |
| <p>The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).</p> | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline, Week 12 | |

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 137 ^[77] | 243 ^[78] | 256 ^[79] | 242 ^[80] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | -0.8 (± 1.37) | -16.4 (± 1.04) | -16.0 (± 1.01) | -18.1 (± 1.04) |

Notes:

[77] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[78] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[79] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[80] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

Statistical analyses

| Statistical analysis title | WPAI-PSO Statistical Analysis 7 |
|---|----------------------------------|
| Statistical analysis description: | |
| Presenteeism Score | |
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 380 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.01 |
| Method | ANCOVA |

| Statistical analysis title | WPAI-PSO Statistical Analysis 8 |
|---|---|
| Statistical analysis description: | |
| Presenteeism | |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 393 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| Statistical analysis title | WPAI-PSO Statistical Analysis 9 |
|---|---|
| Statistical analysis description: | |
| Presenteeism Score | |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 379 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

Secondary: Change From Baseline in Work Productivity Loss Score of WPAI-PSO

| | |
|-----------------|--|
| End point title | Change From Baseline in Work Productivity Loss Score of WPAI-PSO |
|-----------------|--|

End point description:

The WPAI-PSO is a 6-item instrument used to assess the impact of psoriasis on productivity impairment within the past 7 days. It has four domains: absenteeism, presenteeism (reduced productivity while at work), an overall work impairment score, and impairment in daily activities performed outside of work. Four scores are derived as percentages: absenteeism, presenteeism, overall work impairment (absenteeism and presenteeism), and impairment in activities performed outside of work. Percentage is calculated as: each score * 100 and ranged from 0 to 100. Higher scores indicate greater impairment in productivity. LS Means in each WPAI-PSO score were calculated using the ANCOVA model with treatment, pooled center and baseline WPAI-PSO score. Missing data was imputed by last observation carried forward (LOCF).

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

End point timeframe:

Baseline, Week 12

| End point values | Placebo | 50 mg Etanercept (ETN) | 80 mg ixekizumab Dosing Regimen 2 (Q4W) | 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
|-------------------------------------|---------------------|------------------------|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 120 ^[81] | 216 ^[82] | 228 ^[83] | 216 ^[84] |
| Units: Units on a Scale | | | | |
| least squares mean (standard error) | 0.6 (± 1.59) | -17.4 (± 1.20) | -16.7 (± 1.16) | -19.3 (± 1.19) |

Notes:

[81] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[82] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[83] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

[84] - All randomized participants and had at least one post-dose measurement of WPAI-PSO.

Statistical analyses

| | |
|----------------------------|----------------------------------|
| Statistical analysis title | WPAI-PSO Statistical Analysis 10 |
|----------------------------|----------------------------------|

Statistical analysis description:

Work Productively Loss Score

| | |
|---|----------------------------------|
| Comparison groups | Placebo v 50 mg Etanercept (ETN) |
| Number of subjects included in analysis | 336 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|----------------------------|----------------------------------|
| Statistical analysis title | WPAI-PSO Statistical Analysis 11 |
|----------------------------|----------------------------------|

Statistical analysis description:

Work Productively Loss Score

| | |
|---|---|
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 2 (Q4W) |
| Number of subjects included in analysis | 348 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

| | |
|---|---|
| Statistical analysis title | WPAI-PSO Statistical Analysis 12 |
| Statistical analysis description: Work Productively Loss Score | |
| Comparison groups | Placebo v 80 mg ixekizumab Dosing Regimen 1 (Q2W) |
| Number of subjects included in analysis | 336 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | ANCOVA |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Induction, Long Term Extension and Follow-Up Periods

Adverse event reporting additional description:

I1F-MC-RHBC

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 22.0 |
|--------------------|------|

Reporting groups

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

Reporting group description: -

| | |
|-----------------------|------------------|
| Reporting group title | 50 mg Etanercept |
|-----------------------|------------------|

Reporting group description: -

| | |
|-----------------------|---|
| Reporting group title | 80 mg Ixekizumab Dosing Regimen 2 (Q4W) |
|-----------------------|---|

Reporting group description: -

| | |
|-----------------------|---|
| Reporting group title | 80 mg Ixekizumab Dosing Regimen 1 (Q2W) |
|-----------------------|---|

Reporting group description: -

| | |
|-----------------------|----------------------------------|
| Reporting group title | PBO/IXE80Q4W Long term extension |
|-----------------------|----------------------------------|

Reporting group description: -

| | |
|-----------------------|----------------------------------|
| Reporting group title | ETN/IXE80Q4W Long term extension |
|-----------------------|----------------------------------|

Reporting group description: -

| | |
|-----------------------|---------------------------------------|
| Reporting group title | IXE80Q4W/IXE80Q4W Long term extension |
|-----------------------|---------------------------------------|

Reporting group description: -

| | |
|-----------------------|---------------------------------------|
| Reporting group title | IXE80Q2W/IXE80Q4W Long term extension |
|-----------------------|---------------------------------------|

Reporting group description: -

| | |
|-----------------------|----------------------|
| Reporting group title | PBO follow-up period |
|-----------------------|----------------------|

Reporting group description: -

| | |
|-----------------------|----------------------|
| Reporting group title | ETN follow-up period |
|-----------------------|----------------------|

Reporting group description: -

| | |
|-----------------------|---------------------------|
| Reporting group title | IXE80Q4W follow-up period |
|-----------------------|---------------------------|

Reporting group description: -

| | |
|-----------------------|---------------------------|
| Reporting group title | IXE80Q2W follow-up period |
|-----------------------|---------------------------|

Reporting group description: -

| Serious adverse events | Placebo | 50 mg Etanercept | 80 mg Ixekizumab Dosing Regimen 2 (Q4W) |
|---|-----------------|------------------|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 193 (2.59%) | 8 / 382 (2.09%) | 6 / 382 (1.57%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| basal cell carcinoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign lung neoplasm | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign neoplasm of thyroid gland | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bone cancer metastatic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carcinoid tumour of the duodenum | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholesteatoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ewing's sarcoma metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gallbladder cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic adenoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 1 / 382 (0.26%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hodgkin's disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hodgkin's disease mixed cellularity stage unspecified alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| invasive breast carcinoma alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to central nervous system alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to liver alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to lung alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myelodysplastic syndrome alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-hodgkin's lymphoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| oesophageal adenocarcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian germ cell teratoma benign alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 56 (0.00%) | 0 / 113 (0.00%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pituitary tumour benign alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 137 (0.00%) | 0 / 269 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[3] | 0 / 137 (0.00%) | 0 / 269 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| rectal adenocarcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal adenoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma stage ii alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial sarcoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine leiomyoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[4] | 0 / 56 (0.00%) | 1 / 113 (0.88%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vulval cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed ^[5] | 0 / 56 (0.00%) | 0 / 113 (0.00%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| air embolism | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aortic aneurysm | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deep vein thrombosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic vascular disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertensive crisis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral arterial occlusive disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| varicose vein alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| coronary artery bypass alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fracture treatment alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric bypass alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia repair alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hysterectomy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[6] | 0 / 56 (0.00%) | 0 / 113 (0.00%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| implantable cardiac monitor insertion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| perineal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[7] | 0 / 56 (0.00%) | 0 / 113 (0.00%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| abortion spontaneous | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 0 / 56 (0.00%) | 0 / 113 (0.00%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| polyhydramnios | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 56 (0.00%) | 0 / 113 (0.00%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| premature baby | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| accidental death | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| death | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| drug withdrawal syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| hypersensitivity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sarcoidosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[10] | 0 / 137 (0.00%) | 0 / 269 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| genital haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[11] | 0 / 56 (0.00%) | 1 / 113 (0.88%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[12] | 0 / 137 (0.00%) | 0 / 269 (0.00%) | 1 / 254 (0.39%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine scar | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[13] | 0 / 56 (0.00%) | 0 / 113 (0.00%) | 0 / 128 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| acute respiratory failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoxia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung consolidation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal polyps | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal septum deviation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal turbinate hypertrophy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleural effusion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleurisy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| pulmonary embolism alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary oedema alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| respiratory failure alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sleep apnoea syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| acute stress disorder alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol abuse alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anxiety alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar i disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| burnout syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| confusional state | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| depression | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hallucination | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| major depression alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psychotic disorder alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicidal ideation alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicide attempt alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| alanine aminotransferase increased alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biopsy liver alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood alkaline phosphatase increased alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood bilirubin increased alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gamma-glutamyltransferase increased alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| glomerular filtration rate decreased alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications accident alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| accident at work alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol poisoning | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| avulsion fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carotid artery restenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chemical burn of skin | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clavicle fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| concussion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| contusion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fall alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 1 / 382 (0.26%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femoral neck fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femur fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hand fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| humerus fracture alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incision site haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incisional hernia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| joint dislocation alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower limb fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| meniscus injury alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 1 / 382 (0.26%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| patella fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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|--|-----------------|-----------------|-----------------|
| pelvic fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| post procedural bile leak | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| seroma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skull fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| subdural haematoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tibia fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| upper limb fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound dehiscence | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| laryngocele | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| acute myocardial infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina pectoris | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina unstable | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arteriosclerosis coronary artery | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial flutter | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bradycardia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| cardiac arrest | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure congestive | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardio-respiratory arrest | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery stenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| left ventricular failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial ischaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocarditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palpitations | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral artery embolism | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 1 / 382 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebrovascular accident | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cervicobrachial syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dizziness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| embolic stroke | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| epilepsy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| facial paralysis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhagic cerebral infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| headache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hemiparesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic encephalopathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ischaemic stroke | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lacunar infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| loss of consciousness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| miller fisher syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| paraesthesia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| reversible ischaemic neurological deficit | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sciatica | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| senile dementia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| syncope | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| iron deficiency anaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| vertigo | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| cataract | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 1 / 382 (0.26%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| conjunctivitis allergic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diplopia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| optic ischaemic neuropathy alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| retinal vein thrombosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| anal fissure alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis microscopic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis ulcerative alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| crohn's disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulum oesophageal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric polyps | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastrooesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| haematemesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematochezia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhoidal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhoids | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| inguinal hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intussusception | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestinal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestine polyp | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower gastrointestinal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 1 / 382 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis necrotising | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| rectal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| umbilical hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| upper gastrointestinal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vomiting | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| bile duct obstruction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biliary colic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis acute alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholelithiasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic function abnormal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic steatosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| jaundice cholestatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-alcoholic steatohepatitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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|--|-----------------|-----------------|-----------------|
| Skin and subcutaneous tissue disorders | | | |
| diabetic ulcer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypersensitivity vasculitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palmoplantar keratoderma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psoriasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin lesion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin ulcer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| acute kidney injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 1 / 382 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| calculus urinary | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 1 / 382 (0.26%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrotic syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal artery arteriosclerosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cyst haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal impairment | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ureterolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary incontinence | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| arthralgia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chondrocalcinosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc degeneration | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc protrusion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| knee deformity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| neck pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 1 / 382 (0.26%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| osteonecrosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| plica syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psoriatic arthropathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rheumatic disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spondylolisthesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vertebral foraminal stenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| abscess limb | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anal abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis perforated | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| campylobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cellulitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cellulitis staphylococcal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| cholecystitis infective | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic tonsillitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 1 / 382 (0.26%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clostridium difficile colitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colonic abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cystitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| device related infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic foot infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 1 / 382 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| escherichia sepsis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gas gangrene alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| gastroenteritis escherichia coli | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| groin abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| liver abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| mastoiditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| orchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[14] | 0 / 137 (0.00%) | 0 / 269 (0.00%) | 0 / 254 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteomyelitis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia chlamydial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary tuberculosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | | |
|--|-----------------|-----------------|-----------------|--|
| pyelonephritis acute | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 1 / 382 (0.26%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| pyonephrosis | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| sepsis | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| sinusitis | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| skin bacterial infection | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| soft tissue infection | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| spinal cord abscess | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| staphylococcal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| streptococcal sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tonsillitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tooth abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| urinary tract infection pseudomonal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urosepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 1 / 382 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| dehydration | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic ketoacidosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic metabolic decompensation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hyperinsulinaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoglycaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 1 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vitamin b12 deficiency | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 0 / 382 (0.00%) | 0 / 382 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | 80 mg Ixekizumab Dosing Regimen 1 (Q2W) | PBO/IXE80Q4W Long term extension | ETN/IXE80Q4W Long term extension |
|---|---|-------------------------------------|-------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 9 / 384 (2.34%) | 45 / 183 (24.59%) | 71 / 369 (19.24%) |
| number of deaths (all causes) | 0 | 2 | 4 |
| number of deaths resulting from adverse events | 0 | 1 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| basal cell carcinoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign lung neoplasm alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign neoplasm of thyroid gland alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bone cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carcinoid tumour of the duodenum alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholesteatoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| ewing's sarcoma metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gallbladder cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic adenoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hodgkin's disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hodgkin's disease mixed cellularity stage unspecified alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| invasive breast carcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to central nervous system alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to liver alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to lung alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myelodysplastic syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-hodgkin's lymphoma alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| oesophageal adenocarcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian germ cell teratoma benign alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 1 / 109 (0.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pituitary tumour benign alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 254 (0.00%) | 0 / 129 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[3] | 0 / 254 (0.00%) | 0 / 129 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal adenocarcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| rectal adenoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma stage ii alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial sarcoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| uterine leiomyoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[4] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 0 / 109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vulval cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[5] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 0 / 109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders air embolism alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aortic aneurysm | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deep vein thrombosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic vascular disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertensive crisis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral arterial occlusive disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| varicose vein alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| coronary artery bypass alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fracture treatment alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric bypass alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia repair alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hysterectomy alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[6] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 0 / 109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| implantable cardiac monitor insertion alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| perineal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[7] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 1 / 109 (0.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| abortion spontaneous | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 1 / 109 (0.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| polyhydramnios | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 0 / 109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| premature baby | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| accidental death | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| death | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| drug withdrawal syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| hypersensitivity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sarcoidosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[10] | 0 / 254 (0.00%) | 0 / 129 (0.00%) | 1 / 260 (0.38%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| genital haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[11] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 0 / 109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed ^[12] | 0 / 254 (0.00%) | 0 / 129 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine scar | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[13] | 0 / 130 (0.00%) | 0 / 54 (0.00%) | 0 / 109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| acute respiratory failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoxia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung consolidation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal polyps | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal septum deviation alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 2 / 183 (1.09%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal turbinate hypertrophy alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleural effusion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleurisy alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary embolism alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary oedema alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| respiratory failure alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sleep apnoea syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| acute stress disorder alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol abuse alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anxiety alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar i disorder alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar disorder alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| burnout syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| confusional state | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| depression | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hallucination | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| major depression | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psychotic disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicide attempt | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biopsy liver | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood alkaline phosphatase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood bilirubin increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gamma-glutamyltransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| glomerular filtration rate decreased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| accident | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| accident at work | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol poisoning | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| avulsion fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carotid artery restenosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chemical burn of skin alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clavicle fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| concussion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| contusion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| fall | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 2 / 183 (1.09%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femoral neck fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femur fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hand fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incision site haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incisional hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| joint dislocation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower limb fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| meniscus injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| patella fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pelvic fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| post procedural bile leak | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| seroma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skull fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| subdural haematoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tibia fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| upper limb fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound dehiscence | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| laryngocele | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| acute myocardial infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina pectoris | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina unstable | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arteriosclerosis coronary artery alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial fibrillation alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 2 / 183 (1.09%) | 3 / 369 (0.81%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 11 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial flutter alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bradycardia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac arrest alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure acute alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |

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| cardiac failure congestive alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardio-respiratory arrest alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| coronary artery disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery stenosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| left ventricular failure alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial infarction alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 2 / 183 (1.09%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| myocardial ischaemia alternative dictionary used: MedDRA 22.0 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocarditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palpitations | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral artery embolism | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebrovascular accident | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cervicobrachial syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dizziness alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| embolic stroke alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| epilepsy alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| facial paralysis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhagic cerebral infarction alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| headache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hemiparesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic encephalopathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ischaemic stroke | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lacunar infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| loss of consciousness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| miller fisher syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| paraesthesia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| reversible ischaemic neurological deficit | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sciatica | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| senile dementia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| syncope | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| iron deficiency anaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| vertigo | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| cataract | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| conjunctivitis allergic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diplopia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| optic ischaemic neuropathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| retinal vein thrombosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| anal fissure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis microscopic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis ulcerative | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| crohn's disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulum oesophageal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric polyps alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastritis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastrooesophageal reflux disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematemesis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematochezia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| haemorrhoidal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhoids alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| inguinal hernia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intussusception alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestinal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis necrotising | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| umbilical hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| upper gastrointestinal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vomiting alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| bile duct obstruction alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biliary colic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 2 / 183 (1.09%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis acute alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholelithiasis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic function abnormal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic steatosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| jaundice cholestatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-alcoholic steatohepatitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| diabetic ulcer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypersensitivity vasculitis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palmoplantar keratoderma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psoriasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin lesion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin ulcer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urticaria alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders acute kidney injury alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| calculus urinary alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrolithiasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrotic syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal artery arteriosclerosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cyst haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal impairment alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| ureterolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary incontinence | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| arthralgia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 2 / 183 (1.09%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 11 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chondrocalcinosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc degeneration | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc protrusion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 2 / 183 (1.09%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| knee deformity alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| neck pain alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteoarthritis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 4 / 369 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 8 | 0 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteonecrosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| plica syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| psoriatic arthropathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rheumatic disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spondylolisthesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vertebral foraminal stenosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| abscess limb alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anal abscess alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis perforated alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast abscess alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| campylobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cellulitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 3 / 183 (1.64%) | 4 / 369 (1.08%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 3 | 2 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cellulitis staphylococcal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis infective | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | | |
|--|-----------------|-----------------|-----------------|--|
| chronic tonsillitis | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| clostridium difficile colitis | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| colonic abscess | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| cystitis | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| device related infection | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| diabetic foot infection | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| diverticulitis | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 3 / 183 (1.64%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| escherichia sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gas gangrene | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastroenteritis escherichia coli | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| groin abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| liver abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| mastoiditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| orchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[14] | 0 / 254 (0.00%) | 0 / 129 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteomyelitis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia chlamydial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary tuberculosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyonephrosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin bacterial infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| soft tissue infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal cord abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| staphylococcal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| streptococcal sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tonsillitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tooth abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 3 / 369 (0.81%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection pseudomonal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urosepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Metabolism and nutrition disorders | | | |
| dehydration | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic ketoacidosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic metabolic decompensation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hyperinsulinaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoglycaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 1 / 369 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 1 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 384 (0.00%) | 1 / 183 (0.55%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 2 / 369 (0.54%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vitamin b12 deficiency | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 0 / 183 (0.00%) | 0 / 369 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | IXE80Q4W/IXE80Q4W Long term extension | IXE80Q2W/IXE80Q4W Long term extension | PBO follow-up period |
|---|---------------------------------------|---------------------------------------|----------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 82 / 360 (22.78%) | 55 / 362 (15.19%) | 5 / 157 (3.18%) |
| number of deaths (all causes) | 2 | 3 | 1 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| basal cell carcinoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign lung neoplasm | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign neoplasm of thyroid gland | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bone cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carcinoid tumour of the duodenum alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholesteatoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ewing's sarcoma metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gallbladder cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |

| | | | | |
|--|-----------------|-----------------|-----------------|--|
| hepatic adenoma | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| hodgkin's disease | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| hodgkin's disease mixed cellularity stage unspecified | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| invasive breast carcinoma | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| lung cancer metastatic | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| lung neoplasm | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| metastases to central nervous system | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to liver | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to lung | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myelodysplastic syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-hodgkin's lymphoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| oesophageal adenocarcinoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian germ cell teratoma benign | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 119 (0.00%) | 0 / 121 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| pituitary tumour benign alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 2 / 241 (0.83%) | 2 / 241 (0.83%) | 0 / 108 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[3] | 1 / 241 (0.41%) | 0 / 241 (0.00%) | 0 / 108 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal adenocarcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal adenoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma stage ii alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial sarcoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine leiomyoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[4] | 0 / 119 (0.00%) | 1 / 121 (0.83%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vulval cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[5] | 1 / 119 (0.84%) | 0 / 121 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| air embolism alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aortic aneurysm alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deep vein thrombosis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 2 / 362 (0.55%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic vascular disorder alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertension alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertensive crisis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral arterial occlusive disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| varicose vein alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures coronary artery bypass alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fracture treatment | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric bypass | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia repair | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hysterectomy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[6] | 1 / 119 (0.84%) | 0 / 121 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| implantable cardiac monitor insertion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| perineal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[7] | 0 / 119 (0.00%) | 0 / 121 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Pregnancy, puerperium and perinatal conditions | | | |
| abortion spontaneous | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 2 / 119 (1.68%) | 0 / 121 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| polyhydramnios | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[9] | 0 / 119 (0.00%) | 0 / 121 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| premature baby | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| accidental death | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| death | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| drug withdrawal syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| hypersensitivity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sarcoidosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed ^[10] | 0 / 241 (0.00%) | 0 / 241 (0.00%) | 0 / 108 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| genital haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[11] | 0 / 119 (0.00%) | 0 / 121 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[12] | 0 / 241 (0.00%) | 0 / 241 (0.00%) | 0 / 108 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine scar | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[13] | 0 / 119 (0.00%) | 1 / 121 (0.83%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| acute respiratory failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoxia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung consolidation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal polyps | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal septum deviation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal turbinate hypertrophy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleural effusion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleurisy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary embolism | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary oedema | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| respiratory failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sleep apnoea syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Psychiatric disorders | | | |
| acute stress disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol abuse | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anxiety | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar i disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| burnout syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| confusional state | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| depression | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 2 / 362 (0.55%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hallucination | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| major depression | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psychotic disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicide attempt | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biopsy liver | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood alkaline phosphatase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood bilirubin increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gamma-glutamyltransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| glomerular filtration rate decreased | | | |
| alternative dictionary used: | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| accident | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| accident at work | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol poisoning | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| avulsion fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carotid artery restenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chemical burn of skin alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clavicle fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 3 / 362 (0.83%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| concussion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| contusion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fall alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femoral neck fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| femur fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hand fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incision site haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incisional hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| joint dislocation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower limb fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

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|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| meniscus injury alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 360 (0.83%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| patella fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pelvic fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| post procedural bile leak alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| procedural pain alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rib fracture alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 2 / 362 (0.55%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| seroma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skull fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| subdural haematoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tibia fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| upper limb fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound dehiscence | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| laryngocele | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| acute myocardial infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina pectoris | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina unstable | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 2 / 362 (0.55%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arteriosclerosis coronary artery | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial flutter | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bradycardia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac arrest | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure congestive | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardio-respiratory arrest | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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|---|-----------------|-----------------|-----------------|
| coronary artery disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery stenosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| left ventricular failure alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial infarction alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 360 (0.83%) | 2 / 362 (0.55%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial ischaemia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocarditis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palpitations alternative dictionary used: MedDRA 22.0 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral artery embolism | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| cerebrovascular accident | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cervicobrachial syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dizziness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| embolic stroke | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| epilepsy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| facial paralysis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhagic cerebral infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| headache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hemiparesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| hepatic encephalopathy alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ischaemic stroke alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lacunar infarction alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| loss of consciousness alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| miller fisher syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| paraesthesia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| reversible ischaemic neurological deficit alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sciatica | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| senile dementia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| syncope | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| iron deficiency anaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| vertigo | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| cataract | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| conjunctivitis allergic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diplopia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| optic ischaemic neuropathy alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| retinal vein thrombosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| anal fissure alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis microscopic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis ulcerative alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| crohn's disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 2 / 362 (0.55%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulum oesophageal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric polyps alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| gastritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastroesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematemesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematochezia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhoidal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhoids | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| inguinal hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intussusception | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestinal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestine polyp | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower gastrointestinal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| pancreatitis acute alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis necrotising alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| umbilical hernia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| upper gastrointestinal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vomiting alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders bile duct obstruction alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biliary colic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholelithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 4 / 360 (1.11%) | 4 / 362 (1.10%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| hepatic function abnormal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic steatosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| jaundice cholestatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-alcoholic steatohepatitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| diabetic ulcer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypersensitivity vasculitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palmoplantar keratoderma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psoriasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin lesion alternative dictionary used: MedDRA 22.0 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin ulcer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| acute kidney injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| calculus urinary | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrotic syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal artery arteriosclerosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cyst haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal impairment alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ureterolithiasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary incontinence alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chondrocalcinosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc degeneration | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc protrusion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| knee deformity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| neck pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 4 / 360 (1.11%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 7 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteonecrosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| plica syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psoriatic arthropathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rheumatic disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spondylolisthesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 360 (0.83%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vertebral foraminal stenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| abscess limb | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anal abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis perforated | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| campylobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| cellulitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 360 (0.83%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cellulitis staphylococcal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis infective alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic sinusitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic tonsillitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clostridium difficile colitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colonic abscess alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cystitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| device related infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic foot infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| escherichia sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| gas gangrene | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastroenteritis escherichia coli | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| groin abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| liver abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower respiratory tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| mastoiditis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| orchitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[14] | 1 / 241 (0.41%) | 0 / 241 (0.00%) | 0 / 108 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteomyelitis acute alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 360 (0.83%) | 1 / 362 (0.28%) | 1 / 157 (0.64%) |
| occurrences causally related to treatment / all | 1 / 3 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia chlamydial alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| pulmonary tuberculosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis acute alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyonephrosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sepsis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sinusitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 360 (0.56%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin bacterial infection alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| soft tissue infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal cord abscess alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| staphylococcal infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| streptococcal sepsis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tonsillitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tooth abscess alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| urinary tract infection alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection bacterial alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection pseudomonal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urosepsis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| dehydration alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic ketoacidosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic metabolic decompensation alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hyperinsulinaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoglycaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 360 (0.28%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 1 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 0 / 362 (0.00%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vitamin b12 deficiency | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 360 (0.00%) | 1 / 362 (0.28%) | 0 / 157 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | ETN follow-up period | IXE80Q4W follow-up period | IXE80Q2W follow-up period |
|---|----------------------|---------------------------|---------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 309 (1.62%) | 2 / 305 (0.66%) | 6 / 313 (1.92%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| basal cell carcinoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign lung neoplasm | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign neoplasm of thyroid gland | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bone cancer metastatic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carcinoid tumour of the duodenum | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholesteatoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ewing's sarcoma metastatic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gallbladder cancer | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic adenoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hodgkin's disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hodgkin's disease mixed cellularity stage unspecified | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| invasive breast carcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung neoplasm alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to central nervous system alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to liver alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| metastases to lung alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myelodysplastic syndrome alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-hodgkin's lymphoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| oesophageal adenocarcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian germ cell teratoma benign alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[1] | 0 / 92 (0.00%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pituitary tumour benign alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[2] | 0 / 217 (0.00%) | 0 / 205 (0.00%) | 0 / 209 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| prostate cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[3] | 0 / 217 (0.00%) | 0 / 205 (0.00%) | 0 / 209 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal adenocarcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal adenoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cell carcinoma stage ii alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial sarcoma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine leiomyoma alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed ^[4] | 0 / 92 (0.00%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vulval cancer metastatic alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[5] | 0 / 92 (0.00%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| air embolism alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aortic aneurysm alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deep vein thrombosis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic vascular disorder alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertension alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertensive crisis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral arterial occlusive disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| varicose vein | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| coronary artery bypass | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fracture treatment | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric bypass | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia repair | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hysterectomy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[6] | 0 / 92 (0.00%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| implantable cardiac monitor insertion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| perineal operation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[7] | 0 / 92 (0.00%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| abortion spontaneous | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[8] | 1 / 92 (1.09%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| polyhydramnios | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed ^[9] | 0 / 92 (0.00%) | 1 / 100 (1.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| premature baby | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 1 / 305 (0.33%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| accidental death | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| death | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| drug withdrawal syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| hypersensitivity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sarcoidosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[10] | 0 / 217 (0.00%) | 0 / 205 (0.00%) | 0 / 209 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| genital haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ovarian cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[11] | 0 / 92 (0.00%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostatitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[12] | 0 / 217 (0.00%) | 0 / 205 (0.00%) | 0 / 209 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine scar | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[13] | 0 / 92 (0.00%) | 0 / 100 (0.00%) | 0 / 104 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| acute respiratory failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoxia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung consolidation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal polyps | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal septum deviation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nasal turbinate hypertrophy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleural effusion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| pleurisy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary embolism | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 1 / 305 (0.33%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary oedema | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| respiratory failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sleep apnoea syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| acute stress disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol abuse | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anxiety | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar i disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bipolar disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| burnout syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| confusional state | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| depression | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| hallucination | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| major depression | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psychotic disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| suicide attempt | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biopsy liver | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood alkaline phosphatase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blood bilirubin increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gamma-glutamyltransferase increased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| glomerular filtration rate decreased | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| accident | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| accident at work | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| alcohol poisoning | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| avulsion fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carotid artery restenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chemical burn of skin | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| clavicle fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| concussion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| contusion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fall | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femoral neck fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femur fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hand fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incision site haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| incisional hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| joint dislocation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower limb fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| meniscus injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| patella fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pelvic fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| post procedural bile leak | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| seroma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skull fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| subdural haematoma | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tibia fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| upper limb fracture | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| wound dehiscence | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| laryngocele | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| acute myocardial infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina pectoris | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina unstable | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arteriosclerosis coronary artery | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial flutter | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bradycardia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac arrest | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure congestive | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardio-respiratory arrest | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| coronary artery stenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| left ventricular failure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial ischaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocarditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palpitations | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| cerebral artery embolism | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 309 (0.32%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebrovascular accident | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 309 (0.32%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cervicobrachial syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dizziness | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| embolic stroke | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| epilepsy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| facial paralysis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhagic cerebral infarction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| headache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hemiparesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic encephalopathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| ischaemic stroke | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| lacunar infarction | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| loss of consciousness | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| miller fisher syndrome | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| paraesthesia | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| reversible ischaemic neurological deficit | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| sciatica | | | | |
| alternative dictionary used: MedDRA 22.0 | | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| senile dementia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| syncope | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| iron deficiency anaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| vertigo | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| cataract | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| conjunctivitis allergic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diplopia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| optic ischaemic neuropathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| retinal vein thrombosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| anal fissure | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis microscopic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis ulcerative alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 1 / 305 (0.33%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| crohn's disease alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diarrhoea alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulum oesophageal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric polyps alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastritis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| gastroesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematemesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematochezia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhoidal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhoids | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| inguinal hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intussusception | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestinal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestine polyp alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nausea alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis acute alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| pancreatitis necrotising | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| umbilical hernia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| upper gastrointestinal haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vomiting | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| bile duct obstruction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| biliary colic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholelithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic function abnormal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hepatic steatosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| jaundice cholestatic | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| non-alcoholic steatohepatitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| diabetic ulcer alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypersensitivity vasculitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| palmoplantar keratoderma alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psoriasis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 309 (0.65%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin lesion alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin ulcer alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| acute kidney injury | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| calculus urinary | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrotic syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal artery arteriosclerosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal cyst haemorrhage | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal impairment | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ureterolithiasis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary incontinence | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| arthralgia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chondrocalcinosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc degeneration | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc protrusion | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| knee deformity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| neck pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteonecrosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| plica syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| psoriatic arthropathy | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rheumatic disorder | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spondylolisthesis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovial cyst | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| synovitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vertebral foraminal stenosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| abscess limb | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| anal abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis perforated | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| campylobacter infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cellulitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| cellulitis staphylococcal alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis infective alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic sinusitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic tonsillitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clostridium difficile colitis alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colonic abscess alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cystitis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| device related infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic foot infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| escherichia sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gas gangrene | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastroenteritis escherichia coli | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| groin abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| liver abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| mastoiditis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| orchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[14] | 0 / 217 (0.00%) | 0 / 205 (0.00%) | 0 / 209 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteomyelitis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 1 / 305 (0.33%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia chlamydial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary tuberculosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| pyelonephritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyelonephritis acute | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pyonephrosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skin bacterial infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| soft tissue infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal cord abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| staphylococcal infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| streptococcal sepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tonsillitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tooth abscess | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 309 (0.32%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| urinary tract infection bacterial | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection pseudomonal | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urosepsis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| dehydration | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 1 / 313 (0.32%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic ketoacidosis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetic metabolic decompensation | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hyperinsulinaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypoglycaemia | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| obesity | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 1 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vitamin b12 deficiency | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) | 0 / 313 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification:

This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

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Justification: This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

Justification:

This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

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

| Non-serious adverse events | Placebo | 50 mg Etanercept | 80 mg Ixekizumab Dosing Regimen 2 (Q4W) |
|---|-------------------|-------------------|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 40 / 193 (20.73%) | 90 / 382 (23.56%) | 115 / 382 (30.10%) |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 193 (1.04%) | 9 / 382 (2.36%) | 3 / 382 (0.79%) |
| occurrences (all) | 2 | 9 | 3 |
| Nervous system disorders | | | |
| headache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 5 / 193 (2.59%) | 11 / 382 (2.88%) | 16 / 382 (4.19%) |
| occurrences (all) | 10 | 15 | 23 |
| General disorders and administration site conditions | | | |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 193 (1.55%) | 42 / 382 (10.99%) | 43 / 382 (11.26%) |
| occurrences (all) | 21 | 207 | 99 |
| Gastrointestinal disorders | | | |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 193 (1.04%) | 6 / 382 (1.57%) | 3 / 382 (0.79%) |
| occurrences (all) | 2 | 6 | 7 |
| Respiratory, thoracic and mediastinal disorders | | | |
| cough | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 4 / 382 (1.05%) | 9 / 382 (2.36%) |
| occurrences (all) | 0 | 4 | 10 |
| oropharyngeal pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 3 / 193 (1.55%) 3 | 2 / 382 (0.52%) 2 | 6 / 382 (1.57%) 8 |
| Skin and subcutaneous tissue disorders pruritus alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 1 / 193 (0.52%) 1 | 4 / 382 (1.05%) 4 | 8 / 382 (2.09%) 9 |
| psoriasis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 3 / 193 (1.55%) 3 | 0 / 382 (0.00%) 0 | 5 / 382 (1.31%) 6 |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 4 / 193 (2.07%) 5 | 7 / 382 (1.83%) 7 | 9 / 382 (2.36%) 9 |
| back pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 2 / 193 (1.04%) 2 | 2 / 382 (0.52%) 3 | 8 / 382 (2.09%) 8 |
| Infections and infestations bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 193 (0.00%) 0 | 4 / 382 (1.05%) 4 | 6 / 382 (1.57%) 6 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 193 (0.00%) 0 | 2 / 382 (0.52%) 2 | 2 / 382 (0.52%) 2 |
| influenza alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 193 (0.00%) 0 | 1 / 382 (0.26%) 1 | 1 / 382 (0.26%) 1 |
| nasopharyngitis alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 11 / 193 (5.70%) | 19 / 382 (4.97%) | 29 / 382 (7.59%) |
| occurrences (all) | 12 | 22 | 29 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 193 (0.52%) | 2 / 382 (0.52%) | 7 / 382 (1.83%) |
| occurrences (all) | 1 | 2 | 7 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 2 / 193 (1.04%) | 1 / 382 (0.26%) | 1 / 382 (0.26%) |
| occurrences (all) | 2 | 1 | 1 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 5 / 193 (2.59%) | 8 / 382 (2.09%) | 8 / 382 (2.09%) |
| occurrences (all) | 5 | 8 | 8 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 193 (0.00%) | 3 / 382 (0.79%) | 5 / 382 (1.31%) |
| occurrences (all) | 0 | 3 | 5 |
| vulvovaginal mycotic infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[15] | 1 / 56 (1.79%) | 1 / 113 (0.88%) | 1 / 128 (0.78%) |
| occurrences (all) | 1 | 1 | 1 |

| Non-serious adverse events | 80 mg Ixekizumab Dosing Regimen 1 (Q2W) | PBO/IXE80Q4W Long term extension | ETN/IXE80Q4W Long term extension |
|--|---|-------------------------------------|-------------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 123 / 384 (32.03%) | 117 / 183 (63.93%) | 240 / 369 (65.04%) |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 5 / 384 (1.30%) | 20 / 183 (10.93%) | 30 / 369 (8.13%) |
| occurrences (all) | 6 | 24 | 42 |
| Nervous system disorders | | | |
| headache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed occurrences (all) | 16 / 384 (4.17%) 20 | 9 / 183 (4.92%) 15 | 30 / 369 (8.13%) 47 |
| General disorders and administration site conditions injection site reaction alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 37 / 384 (9.64%) 111 | 18 / 183 (9.84%) 102 | 24 / 369 (6.50%) 186 |
| Gastrointestinal disorders diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 11 / 384 (2.86%) 12 | 10 / 183 (5.46%) 12 | 27 / 369 (7.32%) 29 |
| Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) oropharyngeal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 6 / 384 (1.56%) 6 4 / 384 (1.04%) 4 | 11 / 183 (6.01%) 17 10 / 183 (5.46%) 16 | 23 / 369 (6.23%) 29 16 / 369 (4.34%) 16 |
| Skin and subcutaneous tissue disorders pruritus alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) psoriasis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 7 / 384 (1.82%) 9 5 / 384 (1.30%) 5 | 2 / 183 (1.09%) 2 12 / 183 (6.56%) 14 | 20 / 369 (5.42%) 25 17 / 369 (4.61%) 22 |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|------------------|-------------------|--------------------|
| subjects affected / exposed | 13 / 384 (3.39%) | 17 / 183 (9.29%) | 20 / 369 (5.42%) |
| occurrences (all) | 14 | 17 | 24 |
| back pain | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 7 / 384 (1.82%) | 16 / 183 (8.74%) | 28 / 369 (7.59%) |
| occurrences (all) | 8 | 19 | 32 |
| Infections and infestations | | | |
| bronchitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 384 (0.26%) | 17 / 183 (9.29%) | 20 / 369 (5.42%) |
| occurrences (all) | 1 | 24 | 23 |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 384 (0.78%) | 12 / 183 (6.56%) | 12 / 369 (3.25%) |
| occurrences (all) | 3 | 16 | 13 |
| influenza | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 3 / 384 (0.78%) | 11 / 183 (6.01%) | 20 / 369 (5.42%) |
| occurrences (all) | 3 | 16 | 20 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 26 / 384 (6.77%) | 55 / 183 (30.05%) | 104 / 369 (28.18%) |
| occurrences (all) | 31 | 124 | 196 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 0 / 384 (0.00%) | 4 / 183 (2.19%) | 20 / 369 (5.42%) |
| occurrences (all) | 0 | 6 | 26 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 4 / 384 (1.04%) | 16 / 183 (8.74%) | 10 / 369 (2.71%) |
| occurrences (all) | 4 | 22 | 11 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|-----------------|-------------------|------------------|
| subjects affected / exposed | 8 / 384 (2.08%) | 21 / 183 (11.48%) | 33 / 369 (8.94%) |
| occurrences (all) | 8 | 27 | 58 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 5 / 384 (1.30%) | 6 / 183 (3.28%) | 18 / 369 (4.88%) |
| occurrences (all) | 5 | 9 | 26 |
| vulvovaginal mycotic infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[15] | 1 / 130 (0.77%) | 2 / 54 (3.70%) | 2 / 109 (1.83%) |
| occurrences (all) | 1 | 3 | 3 |

| Non-serious adverse events | IXE80Q4W/IXE80Q4 W Long term extension | IXE80Q2W/IXE80Q4 W Long term extension | PBO follow-up period |
|--|--|--|-------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 236 / 360 (65.56%) | 249 / 362 (68.78%) | 9 / 157 (5.73%) |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 30 / 360 (8.33%) | 26 / 362 (7.18%) | 1 / 157 (0.64%) |
| occurrences (all) | 31 | 31 | 1 |
| Nervous system disorders | | | |
| headache | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 23 / 360 (6.39%) | 27 / 362 (7.46%) | 0 / 157 (0.00%) |
| occurrences (all) | 27 | 39 | 0 |
| General disorders and administration site conditions | | | |
| injection site reaction | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 34 / 360 (9.44%) | 24 / 362 (6.63%) | 0 / 157 (0.00%) |
| occurrences (all) | 291 | 169 | 0 |
| Gastrointestinal disorders | | | |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 14 / 360 (3.89%) | 25 / 362 (6.91%) | 0 / 157 (0.00%) |
| occurrences (all) | 18 | 32 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|--|------------------------|-------------------------|----------------------|
| cough alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 14 / 360 (3.89%) 18 | 26 / 362 (7.18%) 29 | 0 / 157 (0.00%) 0 |
| oropharyngeal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 14 / 360 (3.89%) 18 | 16 / 362 (4.42%) 20 | 0 / 157 (0.00%) 0 |
| Skin and subcutaneous tissue disorders pruritus alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 17 / 360 (4.72%) 22 | 10 / 362 (2.76%) 10 | 0 / 157 (0.00%) 0 |
| psoriasis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 17 / 360 (4.72%) 28 | 15 / 362 (4.14%) 17 | 3 / 157 (1.91%) 3 |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 29 / 360 (8.06%) 38 | 41 / 362 (11.33%) 60 | 0 / 157 (0.00%) 0 |
| back pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 23 / 360 (6.39%) 33 | 30 / 362 (8.29%) 34 | 1 / 157 (0.64%) 1 |
| Infections and infestations bronchitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 24 / 360 (6.67%) 32 | 36 / 362 (9.94%) 47 | 0 / 157 (0.00%) 0 |
| gastroenteritis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 5 / 360 (1.39%) 5 | 18 / 362 (4.97%) 18 | 0 / 157 (0.00%) 0 |

| | | | |
|---|---------------------------|---------------------------|----------------------|
| influenza alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 21 / 360 (5.83%) 23 | 20 / 362 (5.52%) 21 | 0 / 157 (0.00%) 0 |
| nasopharyngitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 107 / 360 (29.72%) 239 | 112 / 362 (30.94%) 222 | 4 / 157 (2.55%) 4 |
| pharyngitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 17 / 360 (4.72%) 20 | 21 / 362 (5.80%) 23 | 0 / 157 (0.00%) 0 |
| sinusitis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 28 / 360 (7.78%) 41 | 27 / 362 (7.46%) 47 | 0 / 157 (0.00%) 0 |
| upper respiratory tract infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 48 / 360 (13.33%) 67 | 42 / 362 (11.60%) 68 | 0 / 157 (0.00%) 0 |
| urinary tract infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 21 / 360 (5.83%) 25 | 21 / 362 (5.80%) 39 | 0 / 157 (0.00%) 0 |
| vulvovaginal mycotic infection alternative dictionary used: MedDRA 22.0 subjects affected / exposed ^[15] occurrences (all) | 6 / 119 (5.04%) 13 | 4 / 121 (3.31%) 5 | 0 / 49 (0.00%) 0 |

| Non-serious adverse events | ETN follow-up period | IXE80Q4W follow-up period | IXE80Q2W follow-up period |
|--|----------------------|---------------------------|---------------------------|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 23 / 309 (7.44%) | 14 / 305 (4.59%) | 15 / 313 (4.79%) |
| Vascular disorders hypertension alternative dictionary used: MedDRA 22.0 | | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed occurrences (all) | 2 / 309 (0.65%) 2 | 0 / 305 (0.00%) 0 | 0 / 313 (0.00%) 0 |
| Nervous system disorders headache alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 2 / 309 (0.65%) 2 | 1 / 305 (0.33%) 1 | 2 / 313 (0.64%) 2 |
| General disorders and administration site conditions injection site reaction alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 309 (0.00%) 0 | 0 / 305 (0.00%) 0 | 0 / 313 (0.00%) 0 |
| Gastrointestinal disorders diarrhoea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 309 (0.00%) 0 | 0 / 305 (0.00%) 0 | 0 / 313 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders cough alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) oropharyngeal pain alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 309 (0.00%) 0 0 / 309 (0.00%) 0 | 1 / 305 (0.33%) 1 0 / 305 (0.00%) 0 | 0 / 313 (0.00%) 0 0 / 313 (0.00%) 0 |
| Skin and subcutaneous tissue disorders pruritus alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) psoriasis alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all) | 0 / 309 (0.00%) 0 10 / 309 (3.24%) 10 | 0 / 305 (0.00%) 0 1 / 305 (0.33%) 1 | 0 / 313 (0.00%) 0 4 / 313 (1.28%) 4 |

| | | | |
|---|---|-----------------|-----------------|
| Musculoskeletal and connective tissue disorders | | | |
| | arthralgia | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 1 / 309 (0.32%) | 1 / 305 (0.33%) |
| | occurrences (all) | 1 | 1 |
| | 1 | 1 | 1 |
| | back pain | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 1 / 309 (0.32%) | 0 / 305 (0.00%) |
| | occurrences (all) | 1 | 0 |
| | 1 | 0 | 0 |
| | 0 | 0 | 0 |
| Infections and infestations | | | |
| | bronchitis | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 0 / 309 (0.00%) | 1 / 305 (0.33%) |
| | occurrences (all) | 0 | 1 |
| | 0 | 1 | 3 |
| | 3 | 3 | 3 |
| | | | |
| | gastroenteritis | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) |
| | occurrences (all) | 0 | 0 |
| | 0 | 0 | 0 |
| | 0 | 0 | 0 |
| | | | |
| | influenza | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 1 / 309 (0.32%) | 0 / 305 (0.00%) |
| | occurrences (all) | 1 | 0 |
| | 1 | 0 | 1 |
| | 1 | 1 | 1 |
| | | | |
| | nasopharyngitis | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 4 / 309 (1.29%) | 5 / 305 (1.64%) |
| | occurrences (all) | 4 | 5 |
| | 4 | 5 | 2 |
| | 2 | 2 | 2 |
| | | | |
| | pharyngitis | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 0 / 309 (0.00%) | 0 / 305 (0.00%) |
| | occurrences (all) | 0 | 0 |
| | 0 | 0 | 1 |
| | 1 | 1 | 1 |
| | 1 | 1 | 1 |
| | | | |
| | sinusitis | | |
| | alternative dictionary used: MedDRA 22.0 | | |
| | subjects affected / exposed | 1 / 309 (0.32%) | 1 / 305 (0.33%) |
| | occurrences (all) | 1 | 1 |
| | 1 | 1 | 1 |
| | 1 | 1 | 1 |
| | | | |
| | upper respiratory tract infection | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 309 (0.32%) | 1 / 305 (0.33%) | 2 / 313 (0.64%) |
| occurrences (all) | 2 | 1 | 2 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed | 1 / 309 (0.32%) | 3 / 305 (0.98%) | 0 / 313 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| vulvovaginal mycotic infection | | | |
| alternative dictionary used: MedDRA 22.0 | | | |
| subjects affected / exposed ^[15] | 0 / 92 (0.00%) | 1 / 100 (1.00%) | 0 / 104 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

Notes:

[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification:

This event is gender specific, only occurring in male and female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 15 March 2012 | <p>Changes to protocol (a):</p> <ul style="list-style-type: none">-Included monthly urine pregnancy testing for women of childbearing potential.-Removed evaluation of joint pain as a secondary objective.-Clarified use of concomitant topical products in the enrollment criteria.-Defined protocol criteria for premedication-Revised the primary analyses for categorical efficacy outcomes to a Cochran-Mantel-Haenszel (CMH) test stratified by center.-Used an MMRM approach for the primary analysis of continuous variables.-Added new details to more clearly define participants with moderate-to-severe heart failure and specified that these participants are excluded.-Revised an enrollment criterion to exclude participants positive for hepatitis B surface antigen or core antibody, regardless of their anti-hepatitis B surface antibody status.-Added a new exclusion and discontinuation criteria to exclude participants who have a condition/contradiction as addressed in local labeling for etanercept.-Revised the hepatic discontinuation rules.-Added a discontinuation rule for participants who develop symptoms suggestive of lupus-like syndrome and are positive for antibodies against double-stranded DNA.-Corrected treatment window for missed doses. |
| 05 November 2012 | <p>Changes to protocol (b):</p> <ul style="list-style-type: none">-Non-inferiority analysis will be reported on both sPGA (0,1) and PASI 75 at Week 12 (non-responder imputation [NRI]) using a fixed margin approach.-The non-inferiority analysis will also be conducted using a US-only population.- The sPGA (0,1) and PASI 75 for the assessment of non-inferiority and superiority of ixekizumab to etanercept have been reordered.- The effect of center on the co-primary endpoints, sPGA (0,1) and PASI 75, will also be investigated based on the actual centers.- Additional details were added regarding the MMRM analysis.- Modified exclusion criterion to allow enrollment of participants who have had previous infection with hepatitis B virus (HBV) with conditions.- Added discontinuation requirement for positive HBV DNA test results.- Updated Study Schedule for hepatitis B monitoring.- Corrected inclusion criterion to require use of spermicide in conjunction with a diaphragm.- Clarified exclusion criterion to more clearly define participants with serious cardiac conditions- Clarified description of appropriate premedication.- Clarified the requirements for rescreening participants for tuberculosis.- Removed DNA collection at Week 24.-PASI 75 assumption for etanercept at Week 12 updated to 53%. |
| 27 February 2015 | <p>Changes to protocol (c):</p> <ul style="list-style-type: none">-Modified major secondary objective for Itch to assess the proportion of participants achieving an Itch NRS ≥ 4 point reduction from baseline for participants who had baseline Itch NRS ≥ 4.-Added language to allow dosing to be increased to 80 mg ixekizumab Q2W after Week 60 during the Long-Term Extension Period (Period 3).-Modified discontinuation criteria.-Modified permitted concomitant medications.-Added language regarding collection of data on cerebrocardiovascular events for adjudication.-Updated hepatic discontinuation criteria.-Updated protocol-specified liver test criteria. |

| | |
|---------------|---|
| 28 March 2017 | Changes to protocol (d): -Added Crohn's disease and ulcerative colitis adjudication. -Added clarity on dosing windows for Long-Term Extension Period. |
|---------------|---|

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported