



Clinical trial results:

A Phase 3b, Multicenter, Open-Label Study to Evaluate the Long-Term Safety and Efficacy of Subcutaneous LY2127399 in Participants with Systemic Lupus Erythematosus (SLE) (Illuminate-X)

Summary

| | |
|--------------------------|----------------------------|
| EudraCT number | 2010-022101-18 |
| Trial protocol | AT HU ES LV BG IT GB DE HR |
| Global end of trial date | 20 October 2015 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 11 April 2018 |
| First version publication date | 11 April 2018 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | H9B-MC-BCDX |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|----------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01488708 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Trial Number : 13811 |

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, 1 877-CTLilly, |
| Scientific contact | Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877-285-4559, |

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 | 06 January 2012 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|-----------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 20 October 2015 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this SLE study is to evaluate the long-term safety and efficacy of LY2127399 in eligible SLE participants who have completed the core studies (NCT01196091) (NCT01205438).

The trial was terminated early due to lack of efficacy.

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 | 06 January 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 | United States: 532 |
| Country: Number of subjects enrolled | Puerto Rico: 15 |
| Country: Number of subjects enrolled | Canada: 6 |
| Country: Number of subjects enrolled | Peru: 69 |
| Country: Number of subjects enrolled | Brazil: 54 |
| Country: Number of subjects enrolled | Mexico: 51 |
| Country: Number of subjects enrolled | Ecuador: 41 |
| Country: Number of subjects enrolled | Argentina: 39 |
| Country: Number of subjects enrolled | Colombia: 30 |
| Country: Number of subjects enrolled | Guatemala: 30 |
| Country: Number of subjects enrolled | Chile: 10 |
| Country: Number of subjects enrolled | Philippines: 59 |
| Country: Number of subjects enrolled | Taiwan: 42 |
| Country: Number of subjects enrolled | Japan: 36 |
| Country: Number of subjects enrolled | Korea, Republic of: 29 |
| Country: Number of subjects enrolled | Thailand: 24 |
| Country: Number of subjects enrolled | Australia: 9 |
| Country: Number of subjects enrolled | New Zealand: 5 |
| Country: Number of subjects enrolled | Malaysia: 2 |

| | |
|--------------------------------------|---|
| Country: Number of subjects enrolled | Singapore: 1 |
| Country: Number of subjects enrolled | Serbia: 63 |
| Country: Number of subjects enrolled | Hungary: 44 |
| Country: Number of subjects enrolled | Poland: 41 |
| Country: Number of subjects enrolled | Russian Federation: 38 |
| Country: Number of subjects enrolled | Ukraine: 31 |
| Country: Number of subjects enrolled | Romania: 23 |
| Country: Number of subjects enrolled | Spain: 22 |
| Country: Number of subjects enrolled | Germany: 15 |
| Country: Number of subjects enrolled | Belarus: 11 |
| Country: Number of subjects enrolled | Bulgaria: 11 |
| Country: Number of subjects enrolled | Latvia: 9 |
| Country: Number of subjects enrolled | Macedonia, the former Yugoslav Republic of: 8 |
| Country: Number of subjects enrolled | Austria: 4 |
| Country: Number of subjects enrolled | Italy: 3 |
| Country: Number of subjects enrolled | Croatia: 2 |
| Country: Number of subjects enrolled | France: 2 |
| Country: Number of subjects enrolled | Tunisia: 40 |
| Country: Number of subjects enrolled | South Africa: 31 |
| Country: Number of subjects enrolled | Israel: 22 |
| Country: Number of subjects enrolled | Egypt: 9 |
| Country: Number of subjects enrolled | United Kingdom: 5 |
| Worldwide total number of subjects | 1518 |
| EEA total number of subjects | 181 |

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) | 1474 |
| From 65 to 84 years | 43 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | LY 2127399 Q2W |

Arm description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

| | |
|--|-------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | LY2127399 every 2 weeks |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

| | |
|------------------|---------------|
| Arm title | LY2127399 Q4W |
|------------------|---------------|

Arm description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

| | |
|--|-------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | LY2127399 every 4 weeks |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

| Number of subjects in period 1 | LY 2127399 Q2W | LY2127399 Q4W |
|--|----------------|---------------|
| Started | 940 | 578 |
| Received at least 1 Dose of Study Drug | 937 | 578 |
| Participated in Follow Up | 810 | 526 |
| Completed | 0 | 0 |
| Not completed | 940 | 578 |
| Study Termination | 940 | 578 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------------|
| Reporting group title | LY 2127399 Q2W |
|-----------------------|----------------|

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

| | |
|-----------------------|---------------|
| Reporting group title | LY2127399 Q4W |
|-----------------------|---------------|

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

| Reporting group values | LY 2127399 Q2W | LY2127399 Q4W | Total |
|---|----------------|---------------|-------|
| Number of subjects | 940 | 578 | 1518 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn - gestational age < 37 0 wk | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 910 | 564 | 1474 |
| From 65 to 84 years | 29 | 14 | 43 |
| 85 years and over | 1 | 0 | 1 |
| Gender, Male/Female Units: | | | |
| Male | 60 | 51 | 111 |
| Female | 880 | 527 | 1407 |
| Race Stratification Units: Subjects | | | |
| Black or African American | 138 | 45 | 183 |
| Non-black or Non-African American | 802 | 533 | 1335 |

| | | | |
|--|--------|--------|-----|
| Race | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 104 | 94 | 198 |
| Asian | 113 | 96 | 209 |
| Black or African American | 130 | 33 | 163 |
| Native Hawaiian or Other Pacific Islander | 0 | 1 | 1 |
| White | 579 | 337 | 916 |
| Multiple | 14 | 17 | 31 |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 265 | 189 | 454 |
| Not Hispanic or Latino | 612 | 314 | 926 |
| Not Applicable | 63 | 75 | 138 |
| Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA-SLEDAI) Score [1] Mean (Stand | | | |
| Units: units on a scale | | | |
| arithmetic mean | 5.4 | 4.9 | |
| standard deviation | ± 3.81 | ± 3.74 | - |

End points

End points reporting groups

| | |
|-----------------------|----------------|
| Reporting group title | LY 2127399 Q2W |
|-----------------------|----------------|

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

| | |
|-----------------------|---------------|
| Reporting group title | LY2127399 Q4W |
|-----------------------|---------------|

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks.

LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks
Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug.

Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

Primary: Number of Adverse Events (AEs)

| | |
|-----------------|---|
| End point title | Number of Adverse Events (AEs) ^[1] |
|-----------------|---|

End point description:

A summary of other non-serious adverse events and all serious adverse events, regardless of causality, is located in the Reported Adverse Events Section.

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

End point timeframe:

Baseline through 4 years

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was performed as per protocol. It was a number value of Adverse Events (AEs).

| End point values | LY 2127399 Q2W | LY2127399 Q4W | | |
|-----------------------------|--------------------|--------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 937 ^[2] | 578 ^[3] | | |
| Units: participants | | | | |
| number (not applicable) | 73.3 | 65.6 | | |

Notes:

[2] - All participants who received at least 1 dose of study drug.

[3] - All participants who received at least 1 dose of study drug.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with a systemic lupus erythematosus (SLE) responder index (SRI) response

| | |
|-----------------|---|
| End point title | Proportion of participants with a systemic lupus erythematosus (SLE) responder index (SRI) response |
|-----------------|---|

End point description:

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

End point timeframe:

Week 48

| End point values | LY 2127399 Q2W | LY2127399 Q4W | | |
|-----------------------------|-------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[4] | 0 ^[5] | | |
| Units: participants | | | | |
| number (not applicable) | | | | |

Notes:

[4] - Zero participants were analyzed due to early termination of the study.

[5] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with a reduction in steroid dose

| | |
|-----------------|---|
| End point title | Proportion of participants with a reduction in steroid dose |
|-----------------|---|

End point description:

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

End point timeframe:

Baseline through 4 years

| End point values | LY 2127399 Q2W | LY2127399 Q4W | | |
|-----------------------------|-------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[6] | 0 ^[7] | | |
| Units: participants | | | | |
| number (not applicable) | | | | |

Notes:

[6] - Zero participants were analyzed due to early termination of the study.

[7] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in SLE Disease Activity Index

End point title Change in SLE Disease Activity Index

End point description:

End point type Secondary

End point timeframe:

Baseline, 4 years

| End point values | LY 2127399 Q2W | LY2127399 Q4W | | |
|-----------------------------|-------------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[8] | 0 ^[9] | | |
| Units: percent | | | | |
| number (not applicable) | | | | |

Notes:

[8] - Zero participants were analyzed due to early termination of the study.

[9] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Occurrence of new severe SLE flares

End point title Occurrence of new severe SLE flares

End point description:

End point type Secondary

End point timeframe:

Baseline through 4 years

| End point values | LY 2127399 Q2W | LY2127399 Q4W | | |
|-----------------------------|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[10] | 0 ^[11] | | |
| Units: count | | | | |
| number (not applicable) | | | | |

Notes:

[10] - Zero participants were analyzed due to early termination of the study.

[11] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of participants with improvement in Lupus Quality of Life

| | |
|-----------------|--|
| End point title | Proportion of participants with improvement in Lupus Quality of Life |
|-----------------|--|

End point description:

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

End point timeframe:

4 years

| End point values | LY 2127399 Q2W | LY2127399 Q4W | | |
|-----------------------------|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[12] | 0 ^[13] | | |
| Units: percent | | | | |
| number (not applicable) | | | | |

Notes:

[12] - Zero participants were analyzed due to early termination of the study.

[13] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Secondary: Change in anti-double-stranded deoxyribonucleic acid level

| | |
|-----------------|--|
| End point title | Change in anti-double-stranded deoxyribonucleic acid level |
|-----------------|--|

End point description:

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

End point timeframe:

Baseline, 4 years

| End point values | LY 2127399 Q2W | LY2127399 Q4W | | |
|-----------------------------|-------------------|-------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[14] | 0 ^[15] | | |
| Units: percent | | | | |
| number (not applicable) | | | | |

Notes:

[14] - Zero participants were analyzed due to early termination of the study.

[15] - Zero participants were analyzed due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

H9B-MC-BCDX

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 17.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | LY 2127399 Q2W Treatment |
|-----------------------|--------------------------|

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks. LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks. Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug. Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

| | |
|-----------------------|--------------------------------|
| Reporting group title | LY2127399 Q4W Treatment Period |
|-----------------------|--------------------------------|

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks. LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks. Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug. Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment.

| | |
|-----------------------|--------------------------|
| Reporting group title | LY 2127399 Q2W Follow Up |
|-----------------------|--------------------------|

Reporting group description:

If participant received LY2127399 in core study, 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 2 weeks (Q2W) for 216 weeks. If participant received placebo during core study: 2 SC injections of 120 mg LY2127399 at Week 0, followed by 1 SC injection of 120 mg LY2127399 Q2W for 216 weeks. Follow up.n

| | |
|-----------------------|-------------------------|
| Reporting group title | LY2127399 Q4W Follow Up |
|-----------------------|-------------------------|

Reporting group description:

If participant received LY2127399 in core study: 1 subcutaneous (SC) injection of 120 mg LY2127399 and 1 SC injection of placebo at Week 0, followed by 1 SC injection of 120 mg LY2127399 every 4 weeks (Q4W) for 216 weeks. If participant received placebo in core study: 2 SC injections of 120 mg LY2127399 at week 0, followed by 1 SC injection of 120 mg LY2127399 Q4W for 216 weeks. LY2127399: 120 mg LY2127399 administered via subcutaneous (SC) injection for 216 weeks. Participants randomized to active treatment in the core studies will remain on the same active dose. In order to ensure that the original randomization arm from the preceding core studies is not unblinded, the first dose in BCDX will be blinded, with all participants receiving 2 injections of blinded study drug. Placebo: Placebo administered via SC injection at first dose to maintain blinding of previous study treatment. Follow up.

| Serious adverse events | LY 2127399 Q2W Treatment | LY2127399 Q4W Treatment Period | LY 2127399 Q2W Follow Up |
|---|-----------------------------|-----------------------------------|-----------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 129 / 937 (13.77%) | 64 / 578 (11.07%) | 41 / 810 (5.06%) |
| number of deaths (all causes) | 5 | 2 | 2 |
| number of deaths resulting from adverse events | 1 | 0 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| basal cell carcinoma | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| benign breast neoplasm | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 vaginal neoplasm | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[1] | 1 / 877 (0.11%) | 0 / 527 (0.00%) | 0 / 810 (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 |
| breast cancer | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| brenner tumour | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[2] | 1 / 877 (0.11%) | 0 / 527 (0.00%) | 0 / 810 (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 |

| | | | | |
|--|-----------------|-----------------|-----------------|--|
| haemangioma | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| neuroendocrine tumour | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| prostate cancer | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[3] | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 50 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| squamous cell carcinoma of skin | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| squamous cell carcinoma of the cervix | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[4] | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 760 (0.00%) | |
| 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 cancer | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[5] | 1 / 877 (0.11%) | 0 / 527 (0.00%) | 0 / 810 (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 | |
| uterine leiomyoma | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed ^[6] | 1 / 877 (0.11%) | 0 / 527 (0.00%) | 0 / 810 (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 |
| Vascular disorders | | | |
| deep vein thrombosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| extremity necrosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| hypertension | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 4 / 937 (0.43%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypotension | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| infarction | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| orthostatic hypotension | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral arterial occlusive disease | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| poor venous access | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| shock haemorrhagic | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| thrombophlebitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| vasculitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| venous occlusion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |

| | | | |
|---|-----------------------------------|-----------------------------------|-----------------------------------|
| venous thrombosis limb alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 937 (0.00%) 0 / 0 0 / 0 | 1 / 578 (0.17%) 0 / 1 0 / 0 | 0 / 810 (0.00%) 0 / 0 0 / 0 |
| Pregnancy, puerperium and perinatal conditions abortion alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[7] occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 877 (0.11%) 0 / 1 0 / 0 | 0 / 527 (0.00%) 0 / 0 0 / 0 | 0 / 810 (0.00%) 0 / 0 0 / 0 |
| abortion spontaneous alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[8] occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 877 (0.11%) 0 / 1 0 / 0 | 1 / 527 (0.19%) 0 / 1 0 / 0 | 0 / 810 (0.00%) 0 / 0 0 / 0 |
| blighted ovum alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[9] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 937 (0.00%) 0 / 0 0 / 0 | 0 / 578 (0.00%) 0 / 0 0 / 0 | 0 / 760 (0.00%) 0 / 0 0 / 0 |
| ectopic pregnancy alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[10] occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 877 (0.11%) 0 / 1 0 / 0 | 0 / 527 (0.00%) 0 / 0 0 / 0 | 1 / 760 (0.13%) 0 / 1 0 / 0 |
| General disorders and administration site conditions death alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all device dislocation | 0 / 937 (0.00%) 0 / 0 0 / 0 | 1 / 578 (0.17%) 0 / 1 0 / 1 | 0 / 810 (0.00%) 0 / 0 0 / 0 |

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|--|-----------------|-----------------|-----------------|
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| implant site erosion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| medical device complication | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 3 / 810 (0.37%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pelvic mass | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 2 / 810 (0.25%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 1 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| drug hypersensitivity | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

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|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[11] | 0 / 60 (0.00%) | 1 / 51 (1.96%) | 0 / 50 (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 |
| dysmenorrhoea alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[12] | 0 / 877 (0.00%) | 1 / 527 (0.19%) | 0 / 760 (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 |
| metrorrhagia alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[13] | 1 / 877 (0.11%) | 0 / 527 (0.00%) | 0 / 810 (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 |
| ovarian cyst alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[14] | 0 / 877 (0.00%) | 1 / 527 (0.19%) | 0 / 810 (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 distress syndrome alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| acute respiratory failure alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| asthma | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atelectasis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 4 / 937 (0.43%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dyspnoea | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| haemoptysis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| hypoxia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| interstitial lung disease alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 2 / 578 (0.35%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pleural fibrosis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 congestion alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary embolism alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 2 / 810 (0.25%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary haemorrhage alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 hypertension alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary oedema alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 airway obstruction alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| anxiety alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| conversion disorder alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| delirium tremens alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| generalised anxiety disorder alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| mental status changes alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| suicide attempt alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| Investigations | | | |
| electrocardiogram qrs complex shortened alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lipase increased alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| ankle fracture alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| bone fissure | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| bronchial injury | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| concussion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| contusion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fall | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femoral neck fracture | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |

| | | | |
|--|-----------------|-----------------|-----------------|
| femur fracture | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| fibula fracture | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gun shot wound | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| head injury | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 injury | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| ligament rupture | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| ligament sprain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| overdose | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 intestinal perforation | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| respiratory fume inhalation disorder | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| road traffic accident | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| spinal compression fracture | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 0 / 578 (0.00%) | 0 / 810 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| subdural haematoma alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vascular pseudoaneurysm alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| angina pectoris alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| atrioventricular block alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrioventricular block complete alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| atrioventricular block second degree alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| bundle branch block bilateral alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 arrest alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| cardiac failure congestive alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| cardio-respiratory arrest alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| 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 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| myocardial fibrosis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| 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 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| pericardial effusion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| right ventricular failure | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tachycardia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 2 / 578 (0.35%) | 0 / 810 (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 |
| tricuspid valve disease | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| Nervous system disorders | | | |
| autonomic nervous system imbalance | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| carotid artery dissection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 disorder | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| epilepsy | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| headache | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| hemiparesis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| iiiird nerve disorder | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |

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|--|-----------------|-----------------|-----------------|--|
| migraine | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 | |
| neuropathy peripheral | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| neuropsychiatric lupus | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 | |
| optic neuritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| subarachnoid haemorrhage | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| syncope | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 2 / 578 (0.35%) | 0 / 810 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| tension headache | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| transient ischaemic attack alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| viith nerve paralysis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| vith nerve disorder alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| Blood and lymphatic system disorders | | | |
| anaemia alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| anaemia macrocytic alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| autoimmune haemolytic anaemia alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| febrile neutropenia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| haemolytic anaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemolytic uraemic syndrome | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 anaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| histiocytosis haematophagic | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| iron deficiency anaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 0 / 578 (0.00%) | 0 / 810 (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 |

| | | | |
|--|-----------------|-----------------|-----------------|
| leukopenia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| lymphopenia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| microcytic anaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| neutropenia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 2 / 578 (0.35%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| thrombocytopenia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| thrombotic thrombocytopenic purpura | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 | | | |
| amaurosis fugax | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cataract | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| diplopia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| eyelid ptosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 | | | |
| abdominal pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 4 / 937 (0.43%) | 2 / 578 (0.35%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| 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 ulcerative | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| constipation | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 ulcer perforation | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| gastritis erosive | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| gastrointestinal haemorrhage | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |

| | | | |
|--|-----------------|-----------------|-----------------|
| gastroesophageal reflux disease alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| haemorrhoidal haemorrhage alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| hiatus hernia alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| intestinal ischaemia alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| intestinal perforation alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| large intestine polyp alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| oesophagitis alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| pancreatitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 acute | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rectal haemorrhage | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| retroperitoneal haemorrhage | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| small intestinal obstruction | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 | | | |
| cholecystitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 3 / 937 (0.32%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| cholecystitis acute alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis chronic alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholelithiasis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| drug-induced liver injury alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| 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 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| liver disorder alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| nodular regenerative hyperplasia alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| angioedema alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dry gangrene alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| mucocutaneous ulceration alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| precancerous skin lesion alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| psoriasis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 ulcer alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 and urinary disorders | | | |
| bladder prolapse | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| calculus ureteric | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| glomerulonephritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hydronephrosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lupus nephritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 2 / 810 (0.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| renal failure acute | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 2 / 578 (0.35%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary retention | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| Endocrine disorders | | | |
| adrenal insufficiency | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| adrenocortical insufficiency acute | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| mineralocorticoid deficiency | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| arthritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| bursitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chondrocalcinosis pyrophosphate | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| costochondritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| intervertebral disc protrusion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| lumbar spinal stenosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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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|--|-----------------|-----------------|-----------------|
| muscle haemorrhage | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| muscular weakness | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| musculoskeletal chest pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| osteonecrosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 8 / 937 (0.85%) | 2 / 578 (0.35%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sle arthritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 osteoarthritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| systemic lupus erythematosus | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 4 / 937 (0.43%) | 3 / 578 (0.52%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tendon disorder | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| Infections and infestations | | | |
| abdominal abscess | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| abscess | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| amoebiasis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 2 / 578 (0.35%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| arthritis bacterial | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bacteraemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| blastocystis infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| brain abscess | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |

| | | | | |
|--|-----------------|-----------------|-----------------|--|
| bronchitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| bronchitis bacterial | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| cellulitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) | |
| occurrences causally related to treatment / all | 1 / 3 | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| cervicitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[15] | 0 / 877 (0.00%) | 1 / 527 (0.19%) | 0 / 810 (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 | |
| cytomegalovirus infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 | |
| diverticulitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 | |
| enterocolitis bacterial | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 urinary tract infection alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| gastroenteritis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 937 (0.21%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| groin abscess alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| herpes zoster alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 1 / 578 (0.17%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| herpes zoster disseminated alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| infectious colitis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| kidney infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lobar pneumonia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| localised infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| meningitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| meningitis cryptococcal | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| meningitis viral | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| oesophageal candidiasis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| ophthalmic herpes zoster | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| oral fungal infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| peritonitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| peritonsillar abscess | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| pharyngotonsillitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |

| | | | |
|--|------------------|-----------------|-----------------|
| pneumococcal sepsis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |
| subjects affected / exposed | 11 / 937 (1.17%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 8 / 12 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia bacterial alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| post procedural infection alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| pyelonephritis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| pyonephrosis alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| respiratory tract infection alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 1 / 578 (0.17%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 1 / 3 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| sepsis syndrome alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| septic shock alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| sinusitis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| staphylococcal sepsis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |

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|--|-----------------|-----------------|-----------------|
| staphylococcal skin infection alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| subcutaneous abscess alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| 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 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| upper respiratory tract infection alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 1 / 578 (0.17%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urinary tract infection alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 3 / 937 (0.32%) | 3 / 578 (0.52%) | 2 / 810 (0.25%) |
| occurrences causally related to treatment / all | 2 / 3 | 2 / 3 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| varicella alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 1 / 578 (0.17%) | 0 / 810 (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 |
| viral infection alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vulval cellulitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[16] | 1 / 877 (0.11%) | 0 / 527 (0.00%) | 0 / 810 (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 |
| Metabolism and nutrition disorders | | | |
| cholesterosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dehydration | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| diabetes mellitus | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 0 / 810 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diabetes mellitus inadequate control | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| hyperglycaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| hypoglycaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 2 / 578 (0.35%) | 0 / 810 (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 |
| ketosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 937 (0.11%) | 0 / 578 (0.00%) | 0 / 810 (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 |
| metabolic acidosis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 937 (0.00%) | 0 / 578 (0.00%) | 1 / 810 (0.12%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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|---|-------------------------|--|--|
| Serious adverse events | LY2127399 Q4W Follow Up | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 38 / 526 (7.22%) | | |
| number of deaths (all causes) | 2 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| basal cell carcinoma | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| benign breast neoplasm | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| benign vaginal neoplasm | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[1] | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| breast cancer | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| brenner tumour | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[2] | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| haemangioma | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| neuroendocrine tumour | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| prostate cancer | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[3] | 1 / 44 (2.27%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-----------------------------------|--|--|--|
| squamous cell carcinoma of skin alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| squamous cell carcinoma of the cervix alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[4] occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 482 (0.21%) 0 / 1 0 / 0 | | | |
| uterine cancer alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[5] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| uterine leiomyoma alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[6] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| Vascular disorders deep vein thrombosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 526 (0.19%) 0 / 1 0 / 0 | | | |
| extremity necrosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| hypertension alternative dictionary used: MedDRA 17.1 | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| hypotension | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| infarction | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| orthostatic hypotension | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| peripheral arterial occlusive disease | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| poor venous access | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| shock haemorrhagic | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|--|-----------------|--|--|--|
| thrombophlebitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| vasculitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| venous occlusion | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| venous thrombosis limb | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pregnancy, puerperium and perinatal conditions | | | | |
| abortion | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[7] | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| abortion spontaneous | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[8] | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| blighted ovum | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | |
|--|-----------------|--|--|
| subjects affected / exposed ^[9] | 1 / 482 (0.21%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| ectopic pregnancy | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[10] | 0 / 482 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| death | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| device dislocation | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| implant site erosion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| medical device complication | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| pelvic mass | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| pyrexia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| drug hypersensitivity | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[11] | 1 / 44 (2.27%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed ^[12] | 1 / 482 (0.21%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| metrorrhagia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed ^[13] | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ovarian cyst | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[14] | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | |
| acute respiratory distress syndrome | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| acute respiratory failure | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| asthma | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| atelectasis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| chronic obstructive pulmonary disease | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| dyspnoea | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| haemoptysis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| hypoxia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| interstitial lung disease | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pleural effusion | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pleural fibrosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|-----------------------------------|--|--|--|
| pulmonary congestion alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| pulmonary embolism alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| pulmonary haemorrhage alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 526 (0.19%) 0 / 1 0 / 1 | | | |
| pulmonary hypertension alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| pulmonary oedema alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| upper airway obstruction alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| Psychiatric disorders anxiety alternative dictionary used: MedDRA 17.1 | | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| conversion disorder | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| delirium tremens | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| depression | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| generalised anxiety disorder | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| mental status changes | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| suicide attempt | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|-----------------|--|--|
| Investigations | | | |
| electrocardiogram qrs complex shortened | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| lipase increased | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| bone fissure | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| bronchial injury | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| concussion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| contusion | | | |

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|--|-----------------|--|--|--|
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| fall | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| femoral neck fracture | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| femur fracture | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| fibula fracture | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| gun shot wound | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| head injury | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| joint injury | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ligament rupture | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ligament sprain | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| muscle strain | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| overdose | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| procedural intestinal perforation | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|-----------------------------------|--|--|--|
| respiratory fume inhalation disorder alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| road traffic accident alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| spinal compression fracture alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| subdural haematoma alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| vascular pseudoaneurysm alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 526 (0.19%) 0 / 1 0 / 0 | | | |
| Cardiac disorders acute myocardial infarction alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| angina pectoris alternative dictionary used: MedDRA 17.1 | | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| atrioventricular block | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| atrioventricular block complete | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| atrioventricular block second degree | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| bundle branch block bilateral | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| cardiac arrest | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| cardiac failure congestive | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-----------------|--|--|--|
| cardio-respiratory arrest | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| coronary artery disease | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| myocardial fibrosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| myocardial infarction | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pericardial effusion | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pericarditis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| right ventricular failure | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

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|---|-----------------|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| tachycardia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| tricuspid valve disease | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| autonomic nervous system imbalance | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| carotid artery dissection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| cerebrovascular disorder | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| epilepsy | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| headache | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| hemiparesis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| iiiird nerve disorder | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| migraine | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| neuropathy peripheral | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| neuropsychiatric lupus | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-----------------|--|--|--|
| optic neuritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| subarachnoid haemorrhage | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| syncope | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| tension headache | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| transient ischaemic attack | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| viith nerve paralysis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| vith nerve disorder | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| anaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| anaemia macrocytic | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| autoimmune haemolytic anaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| febrile neutropenia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| haemolytic anaemia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| haemolytic uraemic syndrome | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| haemorrhagic anaemia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| histiocytosis haematophagic | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| iron deficiency anaemia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| leukopenia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| lymphopenia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| microcytic anaemia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-----------------|--|--|--|
| neutropenia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| thrombocytopenia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| thrombotic thrombocytopenic purpura | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ear and labyrinth disorders | | | | |
| vertigo | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Eye disorders | | | | |
| amaurosis fugax | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| cataract | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| diplopia | | | | |

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|--|-----------------|--|--|--|
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| eyelid ptosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal disorders | | | | |
| abdominal pain | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| colitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| colitis ulcerative | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| constipation | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| gastric ulcer perforation | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| gastritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| gastritis erosive | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| gastrointestinal haemorrhage | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| gastrooesophageal reflux disease | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| haemorrhoidal haemorrhage | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| hiatus hernia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-----------------|--|--|--|
| intestinal ischaemia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| intestinal perforation | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| large intestine polyp | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| oesophagitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pancreatitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pancreatitis acute | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| rectal haemorrhage | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| retroperitoneal haemorrhage alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| small intestinal obstruction alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| cholecystitis alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| cholecystitis acute alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| cholecystitis chronic alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| cholelithiasis alternative dictionary used: MedDRA 17.1 | | | |

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|---|-----------------|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| drug-induced liver injury alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| hepatic function abnormal alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| liver disorder alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| nodular regenerative hyperplasia alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| angioedema alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| dry gangrene alternative dictionary used: MedDRA 17.1 | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| mucocutaneous ulceration | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| precancerous skin lesion | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| psoriasis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| skin ulcer | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| bladder prolapse | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| calculus ureteric | | | |
| alternative dictionary used: MedDRA 17.1 | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| glomerulonephritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| hydronephrosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| lupus nephritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 3 / 526 (0.57%) | | | |
| occurrences causally related to treatment / all | 1 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| nephrolithiasis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| renal failure acute | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| urinary retention | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|--|-----------------|--|--|
| Endocrine disorders | | | |
| adrenal insufficiency | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| adrenocortical insufficiency acute | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| mineralocorticoid deficiency | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| arthritis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| back pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| bursitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| chondrocalcinosis pyrophosphate | | | |

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|--|-----------------|--|--|--|
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| costochondritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| intervertebral disc protrusion | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| lumbar spinal stenosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| muscle haemorrhage | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| muscular weakness | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| musculoskeletal chest pain | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| musculoskeletal pain | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| osteoarthritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| osteonecrosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pain in extremity | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| sle arthritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| spinal osteoarthritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|-----------------------------------|--|--|--|
| systemic lupus erythematosus alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 4 / 526 (0.76%) 0 / 4 0 / 0 | | | |
| tendon disorder alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| Infections and infestations abdominal abscess alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| abscess alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| amoebiasis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| appendicitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| arthritis bacterial alternative dictionary used: MedDRA 17.1 | | | | |

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|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| bacteraemia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| blastocystis infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| brain abscess | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| bronchitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| bronchitis bacterial | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| cellulitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|--|-----------------|--|--|--|
| cervicitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed ^[15] | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| cytomegalovirus infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| diverticulitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| enterocolitis bacterial | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| escherichia urinary tract infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| gastroenteritis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| groin abscess | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| herpes zoster | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 2 / 526 (0.38%) | | | |
| occurrences causally related to treatment / all | 1 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| herpes zoster disseminated | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| infectious colitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| influenza | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| kidney infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| lobar pneumonia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|--|-----------------|--|--|--|
| localised infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| meningitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| meningitis cryptococcal | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| meningitis viral | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| oesophageal candidiasis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ophthalmic herpes zoster | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| oral fungal infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| peritonitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| peritonsillar abscess | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pharyngotonsillitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pneumococcal sepsis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| pneumonia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| pneumonia bacterial | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|--|-----------------------------------|--|--|--|
| post procedural infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 526 (0.19%) 0 / 1 0 / 0 | | | |
| pulmonary tuberculosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| pyelonephritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| pyonephrosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| respiratory tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 526 (0.19%) 0 / 1 0 / 0 | | | |
| sepsis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| sepsis syndrome alternative dictionary used: MedDRA 17.1 | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| septic shock | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| sinusitis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| staphylococcal sepsis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| staphylococcal skin infection | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| subcutaneous abscess | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| tooth abscess | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|--|-----------------------------------|--|--|--|
| upper respiratory tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 526 (0.19%) 0 / 1 0 / 0 | | | |
| urinary tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 3 / 526 (0.57%) 0 / 3 0 / 0 | | | |
| varicella alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| viral infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 526 (0.19%) 0 / 1 0 / 0 | | | |
| vulval cellulitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed ^[16] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| Metabolism and nutrition disorders cholesterosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 526 (0.00%) 0 / 0 0 / 0 | | | |
| dehydration alternative dictionary used: MedDRA 17.1 | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| diabetes mellitus | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| diabetes mellitus inadequate control | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| hyperglycaemia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| hypoglycaemia | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ketosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| metabolic acidosis | | | | |
| alternative dictionary used: MedDRA 17.1 | | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

[16] - 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 or female subjects. The number of subjects exposed has been adjusted accordingly.

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

| Non-serious adverse events | LY 2127399 Q2W Treatment | LY2127399 Q4W Treatment Period | LY 2127399 Q2W Follow Up |
|---|-----------------------------|-----------------------------------|-----------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 464 / 937 (49.52%) | 232 / 578 (40.14%) | 110 / 810 (13.58%) |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 27 / 937 (2.88%) | 8 / 578 (1.38%) | 3 / 810 (0.37%) |
| occurrences (all) | 27 | 10 | 3 |
| Nervous system disorders | | | |
| dizziness | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 18 / 937 (1.92%) | 12 / 578 (2.08%) | 2 / 810 (0.25%) |
| occurrences (all) | 19 | 13 | 2 |
| headache | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 53 / 937 (5.66%) | 28 / 578 (4.84%) | 13 / 810 (1.60%) |
| occurrences (all) | 67 | 34 | 13 |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 19 / 937 (2.03%) | 7 / 578 (1.21%) | 0 / 810 (0.00%) |
| occurrences (all) | 20 | 7 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 20 / 937 (2.13%) | 4 / 578 (0.69%) | 3 / 810 (0.37%) |
| occurrences (all) | 25 | 4 | 4 |
| Gastrointestinal disorders | | | |
| abdominal pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 21 / 937 (2.24%) | 3 / 578 (0.52%) | 2 / 810 (0.25%) |
| occurrences (all) | 21 | 3 | 2 |
| abdominal pain upper | | | |
| alternative dictionary used: | | | |

| | | | |
|---|------------------|------------------|-----------------|
| MedDRA 17.1 | | | |
| subjects affected / exposed | 9 / 937 (0.96%) | 12 / 578 (2.08%) | 5 / 810 (0.62%) |
| occurrences (all) | 9 | 12 | 5 |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 59 / 937 (6.30%) | 18 / 578 (3.11%) | 7 / 810 (0.86%) |
| occurrences (all) | 70 | 21 | 7 |
| gastrooesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 23 / 937 (2.45%) | 7 / 578 (1.21%) | 0 / 810 (0.00%) |
| occurrences (all) | 24 | 7 | 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 34 / 937 (3.63%) | 12 / 578 (2.08%) | 6 / 810 (0.74%) |
| occurrences (all) | 36 | 14 | 6 |
| vomiting | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 21 / 937 (2.24%) | 10 / 578 (1.73%) | 3 / 810 (0.37%) |
| occurrences (all) | 23 | 10 | 4 |
| Respiratory, thoracic and mediastinal disorders | | | |
| cough | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 28 / 937 (2.99%) | 10 / 578 (1.73%) | 9 / 810 (1.11%) |
| occurrences (all) | 29 | 13 | 9 |
| Skin and subcutaneous tissue disorders | | | |
| rash | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 23 / 937 (2.45%) | 6 / 578 (1.04%) | 0 / 810 (0.00%) |
| occurrences (all) | 28 | 8 | 0 |
| Psychiatric disorders | | | |
| anxiety | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 21 / 937 (2.24%) | 10 / 578 (1.73%) | 3 / 810 (0.37%) |
| occurrences (all) | 21 | 11 | 3 |
| insomnia | | | |

| | | | |
|---|--|--|--|
| alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) | 18 / 937 (1.92%) 18 | 12 / 578 (2.08%) 12 | 4 / 810 (0.49%) 4 |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) back pain alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) pain in extremity alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) | 33 / 937 (3.52%) 39 36 / 937 (3.84%) 39 27 / 937 (2.88%) 29 | 12 / 578 (2.08%) 16 17 / 578 (2.94%) 17 6 / 578 (1.04%) 8 | 10 / 810 (1.23%) 11 6 / 810 (0.74%) 6 5 / 810 (0.62%) 5 |
| Infections and infestations bronchitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) gastroenteritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) nasopharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) pharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) sinusitis alternative dictionary used: | 57 / 937 (6.08%) 74 14 / 937 (1.49%) 18 63 / 937 (6.72%) 83 27 / 937 (2.88%) 33 | 26 / 578 (4.50%) 32 16 / 578 (2.77%) 16 40 / 578 (6.92%) 46 15 / 578 (2.60%) 16 | 10 / 810 (1.23%) 10 4 / 810 (0.49%) 4 12 / 810 (1.48%) 12 1 / 810 (0.12%) 1 |

| | | | |
|---|--------------------|------------------|------------------|
| MedDRA 17.1 | | | |
| subjects affected / exposed | 56 / 937 (5.98%) | 17 / 578 (2.94%) | 9 / 810 (1.11%) |
| occurrences (all) | 64 | 28 | 9 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 104 / 937 (11.10%) | 51 / 578 (8.82%) | 18 / 810 (2.22%) |
| occurrences (all) | 142 | 68 | 18 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 106 / 937 (11.31%) | 52 / 578 (9.00%) | 20 / 810 (2.47%) |
| occurrences (all) | 158 | 78 | 21 |

| | | | |
|---|----------------------------|--|--|
| Non-serious adverse events | LY2127399 Q4W Follow Up | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 75 / 526 (14.26%) | | |
| Vascular disorders | | | |
| hypertension | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences (all) | 1 | | |
| Nervous system disorders | | | |
| dizziness | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 526 (0.38%) | | |
| occurrences (all) | 2 | | |
| headache | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 6 / 526 (1.14%) | | |
| occurrences (all) | 6 | | |
| General disorders and administration site conditions | | | |
| fatigue | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences (all) | 1 | | |
| pyrexia | | | |
| alternative dictionary used: | | | |

| | | | |
|---|-----------------|--|--|
| MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences (all) | 1 | | |
| Gastrointestinal disorders | | | |
| abdominal pain | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences (all) | 1 | | |
| abdominal pain upper | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences (all) | 1 | | |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 526 (0.38%) | | |
| occurrences (all) | 2 | | |
| gastrooesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences (all) | 0 | | |
| nausea | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences (all) | 1 | | |
| vomiting | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 1 / 526 (0.19%) | | |
| occurrences (all) | 1 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| cough | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 0 / 526 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|--|--|--|--|
| rash alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) | 1 / 526 (0.19%) 1 | | |
| Psychiatric disorders anxiety alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) insomnia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) | 1 / 526 (0.19%) 1 3 / 526 (0.57%) 3 | | |
| Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) back pain alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) pain in extremity alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) | 3 / 526 (0.57%) 3 4 / 526 (0.76%) 4 3 / 526 (0.57%) 3 | | |
| Infections and infestations bronchitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) gastroenteritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) | 8 / 526 (1.52%) 9 6 / 526 (1.14%) 6 | | |

| | | | |
|---|------------------|--|--|
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 8 / 526 (1.52%) | | |
| occurrences (all) | 8 | | |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 2 / 526 (0.38%) | | |
| occurrences (all) | 2 | | |
| sinusitis | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 3 / 526 (0.57%) | | |
| occurrences (all) | 3 | | |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 11 / 526 (2.09%) | | |
| occurrences (all) | 12 | | |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 17.1 | | | |
| subjects affected / exposed | 16 / 526 (3.04%) | | |
| occurrences (all) | 18 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

| |
|--|
| Insufficient data available for analysis since study terminated early due to lack of efficacy in parent studies. |
|--|

Notes: